

US3742169 (Prod: University of Maryland School of Medicine)

Generated By: KC Joubran

Generated On: 26 Nov 2020 11:15:04

All time stamps listed in this document are displayed in GMT

US3742169

**Form: Participant Creation**

**Generated On: 26 Nov 2020 11:15:04**

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[Participant ID](#)

US3742169

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[mRNA-1273-P301 Completion Guidelines](#)

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US3742169

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:15:04

|                                                                 |                                         |
|-----------------------------------------------------------------|-----------------------------------------|
| Was this visit performed?                                       | Yes <input checked="" type="radio"/>    |
|                                                                 | No <input type="radio"/>                |
| Visit date (dd MMM yyyy)                                        | 31 AUG 2020                             |
| Was visit performed at the participant's home or at the clinic? | Home <input type="radio"/>              |
|                                                                 | Clinic <input checked="" type="radio"/> |
| Folder OID                                                      | SCRN                                    |

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Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:15:04

|                                           |                                                                                                                                                                            |
|-------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Date of Birth (MMM yyyy)                  | (b) (6) 1963                                                                                                                                                               |
| Age                                       | 57                                                                                                                                                                         |
| Age Units                                 | YEARS                                                                                                                                                                      |
| Age (Derived)                             | 57                                                                                                                                                                         |
| Sex                                       | Female <input type="radio"/><br>Male <input checked="" type="radio"/>                                                                                                      |
| Ethnicity                                 | Hispanic or Latino <input type="radio"/><br>Not Hispanic or Latino <input checked="" type="radio"/><br>Not Reported <input type="radio"/><br>Unknown <input type="radio"/> |
| Race (Check All That Apply)               |                                                                                                                                                                            |
| White                                     | False                                                                                                                                                                      |
| Black                                     | False                                                                                                                                                                      |
| Asian                                     | True                                                                                                                                                                       |
| American Indian or Alaska Native          | False                                                                                                                                                                      |
| Native Hawaiian or other Pacific Islander | False                                                                                                                                                                      |
| Other                                     | False                                                                                                                                                                      |
| If race is Other, specify _____           |                                                                                                                                                                            |
| Unknown                                   | False                                                                                                                                                                      |
| Not reported                              | False                                                                                                                                                                      |

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Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:15:04

|                                                 |                                              |
|-------------------------------------------------|----------------------------------------------|
| Date of Informed Consent ( <i>dd MMM yyyy</i> ) | 31 AUG 2020                                  |
| Month and Year of Informed Consent (derived)    | AUG 2020                                     |
| Year of Informed Consent (derived)              | 2020                                         |
| Protocol Version                                | Amendment 1 <input type="radio"/>            |
|                                                 | Amendment 2 <input type="radio"/>            |
|                                                 | Amendment 3 <input checked="" type="radio"/> |
|                                                 | Amendment 4 <input type="radio"/>            |
|                                                 | Amendment 5 <input type="radio"/>            |
| Was participant enrolled in the study?          | Yes <input checked="" type="radio"/>         |
|                                                 | No <input type="radio"/>                     |
| If No, indicate reason for screen fail          | Withdrew Consent <input type="radio"/>       |
|                                                 | Inclusion/Exclusion <input type="radio"/>    |
|                                                 | Cohort Full <input type="radio"/>            |
|                                                 | Other <input type="radio"/>                  |
| If reason for screen fail is Other, specify     |                                              |
| Was this participant screened previously?       | Yes <input type="radio"/>                    |
|                                                 | No <input checked="" type="radio"/>          |
| If Yes, previous participant number             |                                              |
| Enrollment Trigger                              | 1                                            |

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 11:15:04

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 11:15:04

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:15:04

|                                                   |                                                                  |
|---------------------------------------------------|------------------------------------------------------------------|
| Condition                                         | GASTROESOPHAGEAL REFLUX<br>DISEASE                               |
| Start date (dd MMM yyyy)                          | UN UNK 2010                                                      |
| Start date completely unknown                     | False                                                            |
| Condition ongoing at study entry                  | Yes <input checked="" type="radio"/><br>No <input type="radio"/> |
| If No, please specify the stop date (dd MMM yyyy) |                                                                  |
| Stop date completely unknown                      | False                                                            |
| Start Month and Year (derived)                    | JAN 2010                                                         |
| Start Year (derived)                              | 2010                                                             |
| Stop Month and Year (derived)                     |                                                                  |
| Stop Year (derived)                               |                                                                  |



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Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:15:04

|                                                   |                                                                  |
|---------------------------------------------------|------------------------------------------------------------------|
| Condition                                         | HYPOTHYROIDISM                                                   |
| Start date (dd MMM yyyy)                          | UN UNK 1990                                                      |
| Start date completely unknown                     | False                                                            |
| Condition ongoing at study entry                  | Yes <input checked="" type="radio"/><br>No <input type="radio"/> |
| If No, please specify the stop date (dd MMM yyyy) |                                                                  |
| Stop date completely unknown                      | False                                                            |
| Start Month and Year (derived)                    | JAN 1990                                                         |
| Start Year (derived)                              | 1990                                                             |
| Stop Month and Year (derived)                     |                                                                  |
| Stop Year (derived)                               |                                                                  |

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Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:15:04

|                                                   |                                                                  |
|---------------------------------------------------|------------------------------------------------------------------|
| Condition                                         | HYPERTENSION                                                     |
| Start date (dd MMM yyyy)                          | UN UNK 2018                                                      |
| Start date completely unknown                     | False                                                            |
| Condition ongoing at study entry                  | Yes <input checked="" type="radio"/><br>No <input type="radio"/> |
| If No, please specify the stop date (dd MMM yyyy) |                                                                  |
| Stop date completely unknown                      | False                                                            |
| Start Month and Year (derived)                    | JAN 2018                                                         |
| Start Year (derived)                              | 2018                                                             |
| Stop Month and Year (derived)                     |                                                                  |
| Stop Year (derived)                               |                                                                  |

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Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:15:04

|                                                         |                                                                  |
|---------------------------------------------------------|------------------------------------------------------------------|
| Condition                                               | ASTHMA                                                           |
| Start date (dd MMM yyyy)                                | UN UNK 2000                                                      |
| Start date completely unknown                           | False                                                            |
| Condition ongoing at study entry                        | Yes <input checked="" type="radio"/><br>No <input type="radio"/> |
| If No, please specify the stop date (dd MMM yyyy) _____ |                                                                  |
| Stop date completely unknown                            | False                                                            |
| Start Month and Year (derived)                          | JAN 2000                                                         |
| Start Year (derived)                                    | 2000                                                             |
| Stop Month and Year (derived)                           | _____                                                            |
| Stop Year (derived)                                     | _____                                                            |

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Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:15:04

|                                                   |                                                                  |
|---------------------------------------------------|------------------------------------------------------------------|
| Condition                                         | ENVIRONMENTAL ALLERGIES                                          |
| Start date (dd MMM yyyy)                          | UN UNK 1990                                                      |
| Start date completely unknown                     | False                                                            |
| Condition ongoing at study entry                  | Yes <input checked="" type="radio"/><br>No <input type="radio"/> |
| If No, please specify the stop date (dd MMM yyyy) |                                                                  |
| Stop date completely unknown                      | False                                                            |
| Start Month and Year (derived)                    | JAN 1990                                                         |
| Start Year (derived)                              | 1990                                                             |
| Stop Month and Year (derived)                     |                                                                  |
| Stop Year (derived)                               |                                                                  |

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Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:15:04

|                                                   |                                                                  |
|---------------------------------------------------|------------------------------------------------------------------|
| Condition                                         | LEFT OUTER THIGH PAIN                                            |
| Start date (dd MMM yyyy)                          | UN JAN 2020                                                      |
| Start date completely unknown                     | False                                                            |
| Condition ongoing at study entry                  | Yes <input checked="" type="radio"/><br>No <input type="radio"/> |
| If No, please specify the stop date (dd MMM yyyy) |                                                                  |
| Stop date completely unknown                      | False                                                            |
| Start Month and Year (derived)                    | JAN 2020                                                         |
| Start Year (derived)                              | 2020                                                             |
| Stop Month and Year (derived)                     |                                                                  |
| Stop Year (derived)                               |                                                                  |

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Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:04

|                                           |                                      |
|-------------------------------------------|--------------------------------------|
| Were vital signs assessed?                | Yes <input checked="" type="radio"/> |
|                                           | No <input type="radio"/>             |
| Date of assessment ( <i>dd MMM yyyy</i> ) | 31 AUG 2020                          |
| Time of assessment ( <i>00:00-23:59</i> ) | 08:22 (24 HR)                        |
| Vital Signs Date and Time (derived)       | 31 AUG 2020 08:22                    |
| Height ( <i>xxx.x</i> )                   | 65.8 in                              |
| Weight ( <i>xxx.x</i> )                   | 189.5 lb                             |
| BMI ( <i>xxx.x</i> )                      | 30.83666 kg/m <sup>2</sup>           |
| BMI units                                 | KG/M2                                |
| Temperature ( <i>xxx.x</i> )              | ND - Not Done                        |
| Route of measurement                      | Oral <input type="radio"/>           |
|                                           | Axillary <input type="radio"/>       |
|                                           | Other <input type="radio"/>          |
| If Other, specify                         |                                      |
| Pulse ( <i>xxx</i> )                      | ND - Not Done                        |
| Pulse units                               | BPM                                  |
| Respiratory Rate ( <i>xxx</i> )           | ND - Not Done                        |
| Respiratory Rate units                    | BREATHS/MIN                          |
| Systolic Blood Pressure ( <i>xxx</i> )    | ND - Not Done                        |
| Systolic Blood Pressure units             | MMHG                                 |
| Diastolic Blood Pressure ( <i>xxx</i> )   | ND - Not Done                        |
| Diastolic Blood Pressure units            | MMHG                                 |
| Height (derived)                          |                                      |
| Weight (derived)                          |                                      |

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Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 11:15:04

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

31 AUG 2020

*Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.*

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Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:15:04

#### Occupational Risk

|                                                                                                                                                         |                                      |
|---------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------|
| <b>Healthcare workers</b> (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)                                            | Yes <input type="radio"/>            |
|                                                                                                                                                         | No <input checked="" type="radio"/>  |
| <b>Emergency Response</b> (e.g., Law enforcement officers, Firefighters, emergency medical service workers)                                             | Yes <input type="radio"/>            |
|                                                                                                                                                         | No <input checked="" type="radio"/>  |
| <b>Retail or Restaurant Operations</b> , particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores) | Yes <input type="radio"/>            |
|                                                                                                                                                         | No <input checked="" type="radio"/>  |
| <b>Manufacturing &amp; Production Operations</b> with inherent overcrowding (e.g., factory workers, meat/food processing plants)                        | Yes <input type="radio"/>            |
|                                                                                                                                                         | No <input checked="" type="radio"/>  |
| <b>Warehouse shipping and fulfillment centers</b> and jobs (e.g., Amazon facilities)                                                                    | Yes <input type="radio"/>            |
|                                                                                                                                                         | No <input checked="" type="radio"/>  |
| <b>Transportation and delivery services</b> (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)                                     | Yes <input type="radio"/>            |
|                                                                                                                                                         | No <input checked="" type="radio"/>  |
| <b>Border Protection and Military Personnel</b> (e.g., TSA, custom and border protection agents, military personnel not social distancing)              | Yes <input type="radio"/>            |
|                                                                                                                                                         | No <input checked="" type="radio"/>  |
| <b>Personal Care and in-home services</b> (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)                | Yes <input type="radio"/>            |
|                                                                                                                                                         | No <input checked="" type="radio"/>  |
| <b>Hospitality and Tourism Workers</b> (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)                                          | Yes <input type="radio"/>            |
|                                                                                                                                                         | No <input checked="" type="radio"/>  |
| <b>Pastoral, Social or Public Health Workers</b> requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy) | Yes <input type="radio"/>            |
|                                                                                                                                                         | No <input checked="" type="radio"/>  |
| <b>Educators and Students</b> (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)                  | Yes <input checked="" type="radio"/> |
|                                                                                                                                                         | No <input type="radio"/>             |
| <b>Other</b>                                                                                                                                            | Yes <input type="radio"/>            |
|                                                                                                                                                         | No <input checked="" type="radio"/>  |

#### Specify

#### Location and Living Circumstances Risk (check all that apply)

|                                                                                                                                              |       |
|----------------------------------------------------------------------------------------------------------------------------------------------|-------|
| <b>No Risk Identified</b>                                                                                                                    | True  |
| <b>Resides in Nursing Home or Assisted Living Facility</b>                                                                                   | False |
| <b>Resides in Multi-family dwelling</b> (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs) | False |



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Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:15:04

|                                                                                                                                        |       |
|----------------------------------------------------------------------------------------------------------------------------------------|-------|
| <b>Resides in high density housing</b> (e.g., high rise apartments with shared entrances or elevators)                                 | False |
| <b>Resides in low density, multi-family setting without</b> (e.g., apartments complex without shared entrances or elevators, duplexes) | False |
| <b>Resides in a single family home</b> (i.e., detached housing)                                                                        | False |
| <b>Other</b>                                                                                                                           | False |
| <b>Specify</b>                                                                                                                         |       |

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:15:04

|                                                                 |                                         |
|-----------------------------------------------------------------|-----------------------------------------|
| Was this visit performed?                                       | Yes <input checked="" type="radio"/>    |
|                                                                 | No <input type="radio"/>                |
| Visit date (dd MMM yyyy)                                        | 31 AUG 2020                             |
| Was visit performed at the participant's home or at the clinic? | Home <input type="radio"/>              |
|                                                                 | Clinic <input checked="" type="radio"/> |
| Folder OID                                                      | VISIT1                                  |

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:15:04

What was the date of randomization? (dd MMM yyyy) 31 AUG 2020

What was the participant's randomization number? 145292

In what Cohort was the participant enrolled?   
 >=18 and <65 years and not at risk ☐   
 >=18 and <65 years and at risk ☒   
 >=65 years ☐

If participant is considered at risk, please check all that apply (If any are checked as Yes, please ensure the actual condition is recorded on the Medical History form)

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma) Yes ☒   
 No ☐

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension) Yes ☐   
 No ☒

Severe obesity (body mass index > or = 40kg/m2) Yes ☐   
 No ☒

Diabetes (Type I, Type 2, or gestational) Yes ☐   
 No ☒

Liver Disease Yes ☐   
 No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐   
 No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:15:04

|        |               |
|--------|---------------|
| Height | ND - Not Done |
| Weight | ND - Not Done |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:15:04

|                                     |                                                                                                        |
|-------------------------------------|--------------------------------------------------------------------------------------------------------|
| Height                              | ND - Not Done                                                                                          |
| Weight                              | ND - Not Done                                                                                          |
| Timepoint                           | Pre-Dose <input checked="" type="radio"/><br>Post-Dose <input type="radio"/>                           |
| Were vital signs assessed?          | Yes <input checked="" type="radio"/><br>No <input type="radio"/>                                       |
| Date of assessment (dd MMM yyyy)    | 31 AUG 2020                                                                                            |
| Time of assessment (00:00-23:59)    | 08:22 (24 HR)                                                                                          |
| Vital Signs Date and Time (derived) | 31 AUG 2020 08:22                                                                                      |
| Temperature (xxx.x)                 | 097.9 F                                                                                                |
| Route of measurement                | Oral <input checked="" type="radio"/><br>Axillary <input type="radio"/><br>Other <input type="radio"/> |
| If Other, specify                   |                                                                                                        |
| Pulse (xxx)                         | 061 beats/min                                                                                          |
| Pulse units                         | BPM                                                                                                    |
| Respiratory Rate (xxx)              | 16 breaths/min                                                                                         |
| Respiratory Rate units              | BREATHS/MIN                                                                                            |
| Systolic Blood Pressure (xxx)       | 120 mmHg                                                                                               |
| Systolic Blood Pressure units       | MMHG                                                                                                   |
| Diastolic Blood Pressure (xxx)      | 080 mmHg                                                                                               |
| Diastolic Blood Pressure units      | MMHG                                                                                                   |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:15:04

|                                     |                                                                                                        |
|-------------------------------------|--------------------------------------------------------------------------------------------------------|
| Height                              | ND - Not Done                                                                                          |
| Weight                              | ND - Not Done                                                                                          |
| Timepoint                           | Pre-Dose <input type="radio"/><br>Post-Dose <input checked="" type="radio"/>                           |
| Were vital signs assessed?          | Yes <input checked="" type="radio"/><br>No <input type="radio"/>                                       |
| Date of assessment (dd MMM yyyy)    | 31 AUG 2020                                                                                            |
| Time of assessment (00:00-23:59)    | 10:07 (24 HR)                                                                                          |
| Vital Signs Date and Time (derived) | 31 AUG 2020 10:07                                                                                      |
| Temperature (xxx.x)                 | 97.8 F                                                                                                 |
| Route of measurement                | Oral <input type="radio"/><br>Axillary <input type="radio"/><br>Other <input checked="" type="radio"/> |
| If Other, specify                   | FOREHEAD                                                                                               |
| Pulse (xxx)                         | 066 beats/min                                                                                          |
| Pulse units                         | BPM                                                                                                    |
| Respiratory Rate (xxx)              | 20 breaths/min                                                                                         |
| Respiratory Rate units              | BREATHS/MIN                                                                                            |
| Systolic Blood Pressure (xxx)       | 122 mmHg                                                                                               |
| Systolic Blood Pressure units       | MMHG                                                                                                   |
| Diastolic Blood Pressure (xxx)      | 80 mmHg                                                                                                |
| Diastolic Blood Pressure units      | MMHG                                                                                                   |

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Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 11:15:04

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

*Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.*

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:15:04

|                                                                                                              |                                                                    |
|--------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------|
| Was study treatment given?                                                                                   | Yes <input checked="" type="radio"/>                               |
|                                                                                                              | No <input type="radio"/>                                           |
| If No, reason not given                                                                                      | Participant declined due to Adverse Event <input type="radio"/>    |
|                                                                                                              | Physician withheld dose due to Adverse Event <input type="radio"/> |
|                                                                                                              | Death <input type="radio"/>                                        |
|                                                                                                              | Lost To Follow-Up <input type="radio"/>                            |
|                                                                                                              | Physician Decision <input type="radio"/>                           |
|                                                                                                              | Pregnancy <input type="radio"/>                                    |
|                                                                                                              | Protocol Deviation <input type="radio"/>                           |
|                                                                                                              | Study Terminated by Sponsor <input type="radio"/>                  |
|                                                                                                              | Withdrawal of Consent by Participant <input type="radio"/>         |
|                                                                                                              | Confirmed COVID-19 <input type="radio"/>                           |
|                                                                                                              | Other <input type="radio"/>                                        |
| If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify |                                                                    |
| What was the study treatment?                                                                                | MRNA-1273 OR PLACEBO                                               |
| What was the treatment date? (dd MMM yyyy)                                                                   | 31 AUG 2020                                                        |
| What was the treatment time? (00:00-23:59)                                                                   | 09:33 (24 HR)                                                      |
| Treatment Date and Time (derived)                                                                            | 31 AUG 2020 09:33                                                  |
| Which arm was used to give treatment?                                                                        | Left Arm <input type="radio"/>                                     |
|                                                                                                              | Right Arm <input checked="" type="radio"/>                         |
| What was the frequency of the study treatment dosing?                                                        | ONCE                                                               |
| What was the route of administration for the study treatment?                                                | INTRAMUSCULAR                                                      |



US3742169

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:15:04

Was the sample collected?

Yes ☒

No ☐

Collection date (*dd MMM yyyy*)

31 AUG 2020

Collection time (*00:00-23:59*)

08:33 (24 HR)

Collection date and time (derived)

31 AUG 2020 08:33

US3742169

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 11:15:04

| Collection date (dd MMM yyyy) |                           |                                 | 31 AUG 2020                        |
|-------------------------------|---------------------------|---------------------------------|------------------------------------|
| Lab Test                      | Was the sample collected? | Collection time (00:00 - 23:59) | Collection date and time (derived) |
| Nasopharyngeal Swab 1         | Yes                       | 08:29                           | 31 AUG 2020 08:29                  |
| Nasopharyngeal Swab 2         | No                        |                                 |                                    |

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Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 11:15:04

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 26 Nov 2020 11:15:04

**TIMEPOINT**

DAY 1, 30 MINUTES AFTER  
VACCINATION (AT STUDY  
CLINIC)

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

Was any **MEDICATION TAKEN** today for pain or fever?

Yes ☐

No ☒

Please confirm reason for pain or fever medication (may select more than one):

PC Time Stamp

31 AUG 2020 10:18

PC Open Date & Time

31 AUG 2020 09:53

PC Close Date & Time

31 AUG 2020 12:23

US3742169

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 26 Nov 2020 11:15:04

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

Was any **MEDICATION TAKEN today for pain or fever?**

Yes ☐

No ☒

Please confirm reason for pain or fever medication (may select more than one):

PC Time Stamp

31 AUG 2020 21:11

PC Open Date & Time

31 AUG 2020 13:18

PC Close Date & Time

01 SEP 2020 11:59

US3742169

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 11:15:04

**TIMEPOINT**

DAY 2

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °F

Was any **MEDICATION TAKEN today for pain or fever**?

Yes ☐

No ☒

Please confirm reason for pain or fever medication (may select more than one):

PC Time Stamp

02 SEP 2020 00:00

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3742169

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 26 Nov 2020 11:15:04

**TIMEPOINT**

DAY 3

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken? Yes ☐  
No ☐

Please record your **TEMPERATURE in °F**

Was any **MEDICATION TAKEN today for pain or fever?** Yes ☐  
No ☐

Please confirm reason for pain or fever medication (may select more than one):

To **TREAT** pain or fever that has already occurred

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time 02 SEP 2020 12:00

PC Close Date & Time 03 SEP 2020 11:59

US3742169

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 11:15:04

**TIMEPOINT**

DAY 4

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

Was any **MEDICATION TAKEN today for pain or fever**?

Yes ☐

No ☒

Please confirm reason for pain or fever medication (may select more than one):

PC Time Stamp

04 SEP 2020 11:15

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59



US3742169

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 26 Nov 2020 11:15:04

**TIMEPOINT**

DAY 5

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

Was any **MEDICATION TAKEN today for pain or fever**?

Yes ☐

No ☒

Please confirm reason for pain or fever medication (may select more than one):

PC Time Stamp

04 SEP 2020 23:14

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3742169

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 26 Nov 2020 11:15:04

**TIMEPOINT**

DAY 6

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

Was any **MEDICATION TAKEN today for pain or fever**?

Yes ☐

No ☒

Please confirm reason for pain or fever medication (may select more than one):

PC Time Stamp

06 SEP 2020 09:05

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3742169

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 26 Nov 2020 11:15:04

---

**TIMEPOINT**

DAY 7

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

Was any **MEDICATION TAKEN today for pain or fever**?

Yes ☐

No ☒

Please confirm reason for pain or fever medication (may select more than one):

PC Time Stamp

07 SEP 2020 10:42

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3742169

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 11:15:04

**TIMEPOINT**

DAY 1, 30 MINUTES AFTER  
VACCINATION (AT STUDY  
CLINIC)

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

None ☒

Does not interfere with activity ☐

Repeated use of over-the-counter  
pain reliever > 24 hours or  
interferes with activity ☐

Any use of prescription pain  
reliever or prevents daily activity ☐

Is there any **REDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Please record - **UNDERARM GLAND SWELLING OR  
TENDERNESS.**

Please select one response below

None ☒

Does not interfere with activity ☐

Repeated use of over-the-counter  
pain reliever > 24 hours or  
interferes with some activity ☐

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

31 AUG 2020 10:18

PC Open Date & Time

31 AUG 2020 09:53

PC Close Date & Time

31 AUG 2020 12:23

US3742169

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 26 Nov 2020 11:15:04

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

None ☐

Does not interfere with activity ☒

Repeated use of over-the-counter  
pain reliever > 24 hours or  
interferes with activity ☐

Any use of prescription pain  
reliever or prevents daily activity ☐

Is there any **REDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Please record - **UNDERARM GLAND SWELLING OR  
TENDERNESS.**

Please select one response below

None ☐

Does not interfere with activity ☒

Repeated use of over-the-counter  
pain reliever > 24 hours or  
interferes with some activity ☐

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

31 AUG 2020 21:14

PC Open Date & Time

31 AUG 2020 13:18

PC Close Date & Time

01 SEP 2020 11:59

US3742169

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 26 Nov 2020 11:15:04

**TIMEPOINT**

DAY 2

Please record - **PAIN AT INJECTION SITE.**

None ☐

Please select one response below

Does not interfere with activity ☒

Repeated use of over-the-counter  
pain reliever > 24 hours or  
interferes with activity ☐

Any use of prescription pain  
reliever or prevents daily activity ☐

Is there any **REDNESS AT INJECTION SITE?**

Yes ☒

No ☐

Please record - **REDNESS AT INJECTION SITE (in mm)**

3

Measure the largest size across any injection site redness with the  
ruler provided.

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Please record - **UNDERARM GLAND SWELLING OR  
TENDERNESS.**

None ☐

Please select one response below

Does not interfere with activity ☒

Repeated use of over-the-counter  
pain reliever > 24 hours or  
interferes with some activity ☐

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

02 SEP 2020 00:00

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3742169

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 26 Nov 2020 11:15:04

**TIMEPOINT**

DAY 3

Please record - **PAIN AT INJECTION SITE.**

None ☐

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter  
pain reliever > 24 hours or  
interferes with activity ☐

Any use of prescription pain  
reliever or prevents daily activity ☐

Is there any **REDNESS AT INJECTION SITE?**

Yes ☐

No ☐

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the  
ruler provided.

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Yes ☐

No ☐

Please record - **SWELLING/HARDNESS AT INJECTION SITE  
(in mm)**

Measure the largest size across any injection site swelling/hardness  
with the ruler provided.

Please record - **UNDERARM GLAND SWELLING OR  
TENDERNESS.**

None ☐

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter  
pain reliever > 24 hours or  
interferes with some activity ☐

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3742169

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 26 Nov 2020 11:15:04

**TIMEPOINT**

DAY 4

Please record - **PAIN AT INJECTION SITE.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter  
pain reliever > 24 hours or  
interferes with activity ☐

Any use of prescription pain  
reliever or prevents daily activity ☐

Is there any **REDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Please record - **UNDERARM GLAND SWELLING OR  
TENDERNESS.**

None ☐

Please select one response below

Does not interfere with activity ☒

Repeated use of over-the-counter  
pain reliever > 24 hours or  
interferes with some activity ☐

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

04 SEP 2020 11:15

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59



US3742169

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 26 Nov 2020 11:15:04

**TIMEPOINT**

DAY 5

Please record - **PAIN AT INJECTION SITE.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter  
pain reliever > 24 hours or  
interferes with activity ☐

Any use of prescription pain  
reliever or prevents daily activity ☐

Is there any **REDNESS AT INJECTION SITE?**

Yes ☒

No ☐

Please record - **REDNESS AT INJECTION SITE (in mm)**

3

Measure the largest size across any injection site redness with the  
ruler provided.

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Please record - **UNDERARM GLAND SWELLING OR  
TENDERNESS.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter  
pain reliever > 24 hours or  
interferes with some activity ☐

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

04 SEP 2020 23:15

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3742169

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 26 Nov 2020 11:15:04

**TIMEPOINT**

DAY 6

Please record - **PAIN AT INJECTION SITE.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter  
pain reliever > 24 hours or  
interferes with activity ☐

Any use of prescription pain  
reliever or prevents daily activity ☐

Is there any **REDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Please record - **UNDERARM GLAND SWELLING OR  
TENDERNESS.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter  
pain reliever > 24 hours or  
interferes with some activity ☐

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

06 SEP 2020 09:05

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3742169

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 26 Nov 2020 11:15:04

**TIMEPOINT**

DAY 7

Please record - **PAIN AT INJECTION SITE.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter  
pain reliever > 24 hours or  
interferes with activity ☐

Any use of prescription pain  
reliever or prevents daily activity ☐

Is there any **REDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Please record - **UNDERARM GLAND SWELLING OR  
TENDERNESS.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter  
pain reliever > 24 hours or  
interferes with some activity ☐

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

07 SEP 2020 10:43

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3742169

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 11:15:04

**TIMEPOINT**

DAY 1, 30 MINUTES AFTER  
VACCINATION (AT STUDY  
CLINIC)

**HEADACHE**

None ☒

No interference with activity ☐

Repeated use of over-the-counter  
pain reliever > 24 hours or some  
interference with activity ☐

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

No interference with activity or  
1-2 episodes/24 hours ☐

Some interference with activity  
or >2 episodes/24 hours ☐

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

US3742169

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 11:15:04

Did you receive any **MEDICAL ATTENTION** (doctor visit,  
**other**) for any illness or symptoms?

No ☒

Yes ☐

|                      |                   |
|----------------------|-------------------|
| PC Time stamp        | 31 AUG 2020 10:19 |
| PC Open Date & Time  | 31 AUG 2020 09:53 |
| PC Close Date & Time | 31 AUG 2020 12:23 |

US3742169

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 11:15:04

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

**HEADACHE**

- None ☐
- No interference with activity ☒
- Repeated use of over-the-counter  
pain reliever > 24 hours or some  
interference with activity ☐
- Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

- None ☐
- No interference with activity ☒
- Some interference with activity ☐
- Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

- None ☐
- No interference with activity ☐
- Some interference with activity ☒
- Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

- None ☐
- No interference with activity ☐
- Some interference with activity ☒
- Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

- None ☐
- No interference with activity or  
1-2 episodes/24 hours ☒
- Some interference with activity  
or >2 episodes/24 hours ☐
- Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

- None ☐
- No interference with activity ☐
- Some interference with activity  
not requiring medical attention ☒
- Prevents daily activity and  
requires medical attention ☐

US3742169

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 11:15:04

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

No ☒

Yes ☐

|                      |                   |
|----------------------|-------------------|
| PC Time stamp        | 31 AUG 2020 21:18 |
| PC Open Date & Time  | 31 AUG 2020 13:18 |
| PC Close Date & Time | 01 SEP 2020 11:59 |

US3742169

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 11:15:04

TIMEPOINT

DAY 2

HEADACHE

None ☐

No interference with activity ☒

Repeated use of over-the-counter  
pain reliever > 24 hours or some  
interference with activity ☐

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☐

No interference with activity or  
1-2 episodes/24 hours ☒

Some interference with activity  
or >2 episodes/24 hours ☐

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☒

Prevents daily activity and  
requires medical attention ☐

Did you receive any **MEDICAL ATTENTION** (doctor visit,  
**other**) for any illness or symptoms?

No ☒



US3742169

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 11:15:04

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 02 SEP 2020 00:01 |
| PC Open Date & Time          | 01 SEP 2020 12:00 |
| PC Close Date & Time         | 02 SEP 2020 11:59 |

US3742169

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 11:15:04

TIMEPOINT

DAY 3

HEADACHE

None ☐

No interference with activity ☐

Repeated use of over-the-counter  
pain reliever > 24 hours or some  
interference with activity ☐

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☐

No interference with activity or  
1-2 episodes/24 hours ☐

Some interference with activity  
or >2 episodes/24 hours ☐

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

Did you receive any **MEDICAL ATTENTION (doctor visit,  
other)** for any illness or symptoms?

No ☐

US3742169

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 11:15:04

|                      |                              |
|----------------------|------------------------------|
|                      | Yes <input type="checkbox"/> |
| PC Time stamp        |                              |
| PC Open Date & Time  | 02 SEP 2020 12:00            |
| PC Close Date & Time | 03 SEP 2020 11:59            |

US3742169

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 11:15:04

TIMEPOINT

DAY 4

HEADACHE

None ☐

No interference with activity ☒

Repeated use of over-the-counter  
pain reliever > 24 hours or some  
interference with activity ☐

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☐

No interference with activity or  
1-2 episodes/24 hours ☒

Some interference with activity  
or >2 episodes/24 hours ☐

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

Did you receive any **MEDICAL ATTENTION** (doctor visit,  
other) for any illness or symptoms?

No ☒

US3742169

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 11:15:04

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 04 SEP 2020 11:16 |
| PC Open Date & Time          | 03 SEP 2020 12:00 |
| PC Close Date & Time         | 04 SEP 2020 11:59 |

US3742169

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 11:15:04

TIMEPOINT

DAY 5

HEADACHE

None ☐

No interference with activity ☒

Repeated use of over-the-counter  
pain reliever > 24 hours or some  
interference with activity ☐

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☐

No interference with activity or  
1-2 episodes/24 hours ☐

Some interference with activity  
or >2 episodes/24 hours ☒

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☒

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

Did you receive any **MEDICAL ATTENTION** (doctor visit,  
other) for any illness or symptoms?

No ☒

US3742169

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 11:15:04

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 04 SEP 2020 23:16 |
| PC Open Date & Time          | 04 SEP 2020 12:00 |
| PC Close Date & Time         | 05 SEP 2020 11:59 |

US3742169

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 11:15:04

TIMEPOINT

DAY 6

HEADACHE

None ☐

No interference with activity ☒

Repeated use of over-the-counter  
pain reliever > 24 hours or some  
interference with activity ☐

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or  
1-2 episodes/24 hours ☐

Some interference with activity  
or >2 episodes/24 hours ☐

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

Did you receive any **MEDICAL ATTENTION** (doctor visit,  
other) for any illness or symptoms?

No ☒



US3742169

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 11:15:04

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 06 SEP 2020 09:06 |
| PC Open Date & Time          | 05 SEP 2020 12:00 |
| PC Close Date & Time         | 06 SEP 2020 11:59 |

US3742169

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 11:15:04

**TIMEPOINT**

DAY 7

**HEADACHE**

None ☒

No interference with activity ☐

Repeated use of over-the-counter  
pain reliever > 24 hours or some  
interference with activity ☐

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

No interference with activity or  
1-2 episodes/24 hours ☐

Some interference with activity  
or >2 episodes/24 hours ☐

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

Did you receive any **MEDICAL ATTENTION** (doctor visit,  
other) for any illness or symptoms?

No ☒

US3742169

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 11:15:04

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 07 SEP 2020 10:44 |
| PC Open Date & Time          | 06 SEP 2020 12:00 |
| PC Close Date & Time         | 07 SEP 2020 11:59 |

US3742169

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(8)

Generated On: 26 Nov 2020 11:15:04

**TIMEPOINT**

DAY 8

Select one response below to indicate the intensity of your **MUSCLE**

None ☐

**ACHES ALL OVER BODY**

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3742169

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(9)

Generated On: 26 Nov 2020 11:15:04

**TIMEPOINT**

DAY 9

Select one response below to indicate the intensity of your **MUSCLE**

**ACHES ALL OVER BODY**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 09 SEP 2020 10:30

PC Open Date & Time 08 SEP 2020 12:00

PC Close Date & Time 09 SEP 2020 11:59

US3742169

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(10)

Generated On: 26 Nov 2020 11:15:04

TIMEPOINT

DAY 10

Select one response below to indicate the intensity of your **MUSCLE**

None ☒

**ACHES ALL OVER BODY**

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp

10 SEP 2020 06:14

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3742169

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(8)

Generated On: 26 Nov 2020 11:15:04

**TIMEPOINT**

DAY 8

Select one response below to indicate the intensity of your **JOINT**

None ☐

**ACHES IN SEVERAL JOINTS**

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3742169

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(9)

Generated On: 26 Nov 2020 11:15:04

---

**TIMEPOINT**

DAY 9

Select one response below to indicate the intensity of your **JOINT**  
**ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

---

PC Time stamp 09 SEP 2020 10:30

PC Open Date & Time 08 SEP 2020 12:00

---

PC Close Date & Time 09 SEP 2020 11:59

---



US3742169

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(10)

Generated On: 26 Nov 2020 11:15:04

**TIMEPOINT**

DAY 10

Select one response below to indicate the intensity of your **JOINT**  
**ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

PC Time stamp 10 SEP 2020 06:14

PC Open Date & Time 09 SEP 2020 12:00

PC Close Date & Time 10 SEP 2020 11:59

US3742169

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 26 Nov 2020 11:15:04

|                                                                                                 |                           |
|-------------------------------------------------------------------------------------------------|---------------------------|
| <b>TIMEPOINT</b>                                                                                | DAY 8                     |
| Did you receive any <b>MEDICAL ATTENTION (doctor visit, other)</b> for any illness or symptoms? | No <input type="radio"/>  |
|                                                                                                 | Yes <input type="radio"/> |
| PC Time stamp                                                                                   |                           |
| PC Open Date & Time                                                                             | 07 SEP 2020 12:00         |
| PC Close Date & Time                                                                            | 08 SEP 2020 11:59         |

US3742169

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(9)

Generated On: 26 Nov 2020 11:15:04

|                                                                                                         |                                                                  |
|---------------------------------------------------------------------------------------------------------|------------------------------------------------------------------|
| <b>TIMEPOINT</b>                                                                                        | DAY 9                                                            |
| Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms? | No <input checked="" type="radio"/><br>Yes <input type="radio"/> |
| PC Time stamp                                                                                           | 09 SEP 2020 10:30                                                |
| PC Open Date & Time                                                                                     | 08 SEP 2020 12:00                                                |
| PC Close Date & Time                                                                                    | 09 SEP 2020 11:59                                                |

US3742169

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(10)

Generated On: 26 Nov 2020 11:15:04

|                                                                                                         |                                                                  |
|---------------------------------------------------------------------------------------------------------|------------------------------------------------------------------|
| <b>TIMEPOINT</b>                                                                                        | DAY 10                                                           |
| Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms? | No <input checked="" type="radio"/><br>Yes <input type="radio"/> |
| PC Time stamp                                                                                           | 10 SEP 2020 06:14                                                |
| PC Open Date & Time                                                                                     | 09 SEP 2020 12:00                                                |
| PC Close Date & Time                                                                                    | 10 SEP 2020 11:59                                                |

US3742169

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:15:04

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

09 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3742169

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:15:04

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742169

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:15:04

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

16 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3742169

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:15:04

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3742169

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:15:04

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (*dd MMM yyyy*)

23 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3742169

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:15:04

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742169

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:15:04

|                                                                 |                                         |
|-----------------------------------------------------------------|-----------------------------------------|
| Was this visit performed?                                       | Yes <input checked="" type="radio"/>    |
|                                                                 | No <input type="radio"/>                |
| Visit date (dd MMM yyyy)                                        | 5 OCT 2020                              |
| Was visit performed at the participant's home or at the clinic? | Home <input type="radio"/>              |
|                                                                 | Clinic <input checked="" type="radio"/> |
| Folder OID                                                      | VISIT2                                  |

US3742169

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:15:04

|                                     |                                           |
|-------------------------------------|-------------------------------------------|
| Timepoint                           | Pre-Dose <input checked="" type="radio"/> |
|                                     | Post-Dose <input type="radio"/>           |
| Were vital signs assessed?          | Yes <input checked="" type="radio"/>      |
|                                     | No <input type="radio"/>                  |
| Date of assessment (dd MMM yyyy)    | 5 OCT 2020                                |
| Time of assessment (00:00-23:59)    | 12:01 (24 HR)                             |
| Vital Signs Date and Time (derived) | 5 OCT 2020 12:01                          |
| Temperature (xxx.x)                 | 097.9 F                                   |
| Route of measurement                | Oral <input checked="" type="radio"/>     |
|                                     | Axillary <input type="radio"/>            |
|                                     | Other <input type="radio"/>               |
| If Other, specify                   |                                           |
| Pulse (xxx)                         | 066 beats/min                             |
| Pulse units                         | BPM                                       |
| Respiratory Rate (xxx)              | 15 breaths/min                            |
| Respiratory Rate units              | BREATHS/MIN                               |
| Systolic Blood Pressure (xxx)       | 117 mmHg                                  |
| Systolic Blood Pressure units       | MMHG                                      |
| Diastolic Blood Pressure (xxx)      | 083 mmHg                                  |
| Diastolic Blood Pressure units      | MMHG                                      |

US3742169

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:15:04

|                                     |                                            |
|-------------------------------------|--------------------------------------------|
| Timepoint                           | Pre-Dose <input type="radio"/>             |
|                                     | Post-Dose <input checked="" type="radio"/> |
| Were vital signs assessed?          | Yes <input type="radio"/>                  |
|                                     | No <input checked="" type="radio"/>        |
| Date of assessment (dd MMM yyyy)    |                                            |
| Time of assessment (00:00-23:59)    |                                            |
| Vital Signs Date and Time (derived) |                                            |
| Temperature (xxx.x)                 |                                            |
| Route of measurement                | Oral <input type="radio"/>                 |
|                                     | Axillary <input type="radio"/>             |
|                                     | Other <input type="radio"/>                |
| If Other, specify                   |                                            |
| Pulse (xxx)                         |                                            |
| Pulse units                         |                                            |
| Respiratory Rate (xxx)              |                                            |
| Respiratory Rate units              |                                            |
| Systolic Blood Pressure (xxx)       |                                            |
| Systolic Blood Pressure units       |                                            |
| Diastolic Blood Pressure (xxx)      |                                            |
| Diastolic Blood Pressure units      |                                            |

US3742169

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:15:04

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

5 OCT 2020

*Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.*

US3742169

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:15:04

Was study treatment given? Yes ☐  
No ☒

If No, reason not given

Participant declined due to ☐  
Adverse Event ☐  
Physician withheld dose due to ☒  
Adverse Event ☐  
Death ☐  
Lost To Follow-Up ☐  
Physician Decision ☐  
Pregnancy ☐  
Protocol Deviation ☐  
Study Terminated by Sponsor ☐  
Withdrawal of Consent by ☐  
Participant ☐  
Confirmed COVID-19 ☐  
Other ☐

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify WITHHELD DUE TO SAE

What was the study treatment? \_\_\_\_\_

What was the treatment date? (dd MMM yyyy) \_\_\_\_\_

What was the treatment time? (00:00-23:59) \_\_\_\_\_

Treatment Date and Time (derived) \_\_\_\_\_

Which arm was used to give treatment? Left Arm ☐  
Right Arm ☐

What was the frequency of the study treatment dosing? \_\_\_\_\_

What was the route of administration for the study treatment? \_\_\_\_\_

US3742169

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:15:04

|                                        |                                      |
|----------------------------------------|--------------------------------------|
| Was the sample collected?              | Yes <input checked="" type="radio"/> |
|                                        | No <input type="radio"/>             |
| Collection date ( <i>dd MMM yyyy</i> ) | 5 OCT 2020                           |
| Collection time ( <i>00:00-23:59</i> ) | 12:06 (24 HR)                        |
| Collection date and time (derived)     | 5 OCT 2020 12:06                     |



US3742169

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 11:15:04

| Collection date (dd MMM yyyy) |                           |                                 | 5 OCT 2020                         |
|-------------------------------|---------------------------|---------------------------------|------------------------------------|
| Lab Test                      | Was the sample collected? | Collection time (00:00 - 23:59) | Collection date and time (derived) |
| Nasopharyngeal Swab 1         | Yes                       | 12:05                           | 5 OCT 2020 12:05                   |
| Nasopharyngeal Swab 2         | No                        |                                 |                                    |

US3742169

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:15:04

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742169

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:15:04

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3742169

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:15:04

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742169

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:15:04

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3742169

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:15:04

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742169

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:15:04

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

26 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3742169

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:15:04

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3742169

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:15:04

|                                                                 |                                         |
|-----------------------------------------------------------------|-----------------------------------------|
| Was this visit performed?                                       | Yes <input checked="" type="radio"/>    |
|                                                                 | No <input type="radio"/>                |
| Visit date (dd MMM yyyy)                                        | 19 NOV 2020                             |
| Was visit performed at the participant's home or at the clinic? | Home <input type="radio"/>              |
|                                                                 | Clinic <input checked="" type="radio"/> |
| Folder OID                                                      | VISIT3                                  |

US3742169

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:04

|                                           |                                     |
|-------------------------------------------|-------------------------------------|
| Were vital signs assessed?                | Yes <input type="radio"/>           |
|                                           | No <input checked="" type="radio"/> |
| Date of assessment ( <i>dd MMM yyyy</i> ) |                                     |
| Time of assessment ( <i>00:00-23:59</i> ) |                                     |
| Vital Signs Date and Time (derived)       |                                     |
| Temperature ( <i>xxx.x</i> )              |                                     |
| Route of measurement                      | Oral <input type="radio"/>          |
|                                           | Axillary <input type="radio"/>      |
|                                           | Other <input type="radio"/>         |
| If Other, specify                         |                                     |
| Pulse ( <i>xxx</i> )                      |                                     |
| Pulse units                               |                                     |
| Respiratory Rate ( <i>xxx</i> )           |                                     |
| Respiratory Rate units                    |                                     |
| Systolic Blood Pressure ( <i>xxx</i> )    |                                     |
| Systolic Blood Pressure units             |                                     |
| Diastolic Blood Pressure ( <i>xxx</i> )   |                                     |
| Diastolic Blood Pressure units            |                                     |
| Height (derived)                          |                                     |
| Weight (derived)                          |                                     |

US3742169

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:15:04

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

*Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.*

US3742169

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:15:04

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

19 NOV 2020

Collection time (00:00-23:59)

12:22 (24 HR)

Collection date and time (derived)

19 NOV 2020 12:22

US3742169

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:15:04

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742169

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:04

| TIMEPOINT                                                                                                                                                                       | DAY 64                                                                                                         |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><br>Yes <input checked="" type="radio"/>                                               |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/><br>Yes <input type="radio"/>                                               |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input checked="" type="radio"/>                                               |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):                                                                           |                                                                                                                |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )                                                                                                            | False                                                                                                          |
| Chills                                                                                                                                                                          | True                                                                                                           |
| Cough                                                                                                                                                                           | False                                                                                                          |
| Shortness of breath                                                                                                                                                             | True                                                                                                           |
| Difficulty breathing                                                                                                                                                            | False                                                                                                          |
| Fatigue                                                                                                                                                                         | True                                                                                                           |
| Muscle aches                                                                                                                                                                    | True                                                                                                           |
| Body aches                                                                                                                                                                      | False                                                                                                          |
| Headache                                                                                                                                                                        | False                                                                                                          |
| New loss of taste                                                                                                                                                               | False                                                                                                          |
| New loss of smell                                                                                                                                                               | False                                                                                                          |
| Sore throat                                                                                                                                                                     | False                                                                                                          |
| Congestion                                                                                                                                                                      | True                                                                                                           |
| Runny nose                                                                                                                                                                      | False                                                                                                          |
| Nausea                                                                                                                                                                          | False                                                                                                          |
| Vomiting                                                                                                                                                                        | False                                                                                                          |
| Diarrhea                                                                                                                                                                        | False                                                                                                          |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?                                        | No <input checked="" type="radio"/><br>Yes <input type="radio"/>                                               |
| Date and time of submission                                                                                                                                                     | 04 NOV 2020 11:09:21                                                                                           |
| Patient Cloud Open Date & Time                                                                                                                                                  | 31 OCT 2020 00:01                                                                                              |
| Patient Cloud Close Date & Time                                                                                                                                                 | 04 NOV 2020 23:59                                                                                              |

US3742169

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:04

| TIMEPOINT                                                                                                                                                                       | DAY 71                                                                                                         |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><br>Yes <input checked="" type="radio"/>                                               |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/><br>Yes <input type="radio"/>                                               |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input checked="" type="radio"/><br>Yes <input type="radio"/>                                               |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):                                                                           |                                                                                                                |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?                                        | No <input type="radio"/><br>Yes <input checked="" type="radio"/>                                               |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/> |
| Date and time of submission                                                                                                                                                     | 09 NOV 2020 12:37:05                                                                                           |
| Patient Cloud Open Date & Time                                                                                                                                                  | 07 NOV 2020 00:01                                                                                              |
| Patient Cloud Close Date & Time                                                                                                                                                 | 11 NOV 2020 23:59                                                                                              |

US3742169

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:04

**TIMEPOINT**

DAY 78

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission

18 NOV 2020 19:37:26

Patient Cloud Open Date & Time

14 NOV 2020 00:01

Patient Cloud Close Date & Time

18 NOV 2020 23:59



US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:04

| TIMEPOINT                                                                                                                                                                       | DAY 61                                                                                              |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):                                                                           |                                                                                                     |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )                                                                                                            | <input type="checkbox"/>                                                                            |
| Chills                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Cough                                                                                                                                                                           | <input type="checkbox"/>                                                                            |
| Shortness of breath                                                                                                                                                             | <input type="checkbox"/>                                                                            |
| Difficulty breathing                                                                                                                                                            | <input type="checkbox"/>                                                                            |
| Fatigue                                                                                                                                                                         | <input type="checkbox"/>                                                                            |
| Muscle aches                                                                                                                                                                    | <input type="checkbox"/>                                                                            |
| Body aches                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Headache                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| New loss of taste                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| New loss of smell                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| Sore throat                                                                                                                                                                     | <input type="checkbox"/>                                                                            |
| Congestion                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Runny nose                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Nausea                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Vomiting                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Diarrhea                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?                                        | No <input type="radio"/><br>Yes <input type="radio"/>                                               |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 OCT 2020 00:01

[Patient Cloud Close Date & Time](#)

01 NOV 2020 23:59

US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:04

| TIMEPOINT                                                                                                                                                                       | DAY 68                                                                                              |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):                                                                           |                                                                                                     |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )                                                                                                            | <input type="checkbox"/>                                                                            |
| Chills                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Cough                                                                                                                                                                           | <input type="checkbox"/>                                                                            |
| Shortness of breath                                                                                                                                                             | <input type="checkbox"/>                                                                            |
| Difficulty breathing                                                                                                                                                            | <input type="checkbox"/>                                                                            |
| Fatigue                                                                                                                                                                         | <input type="checkbox"/>                                                                            |
| Muscle aches                                                                                                                                                                    | <input type="checkbox"/>                                                                            |
| Body aches                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Headache                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| New loss of taste                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| New loss of smell                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| Sore throat                                                                                                                                                                     | <input type="checkbox"/>                                                                            |
| Congestion                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Runny nose                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Nausea                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Vomiting                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Diarrhea                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?                                        | No <input type="radio"/><br>Yes <input type="radio"/>                                               |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

08 NOV 2020 23:59

US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:04

| TIMEPOINT                                                                                                                                                                       | DAY 75                                                                                              |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):                                                                           |                                                                                                     |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )                                                                                                            | <input type="checkbox"/>                                                                            |
| Chills                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Cough                                                                                                                                                                           | <input type="checkbox"/>                                                                            |
| Shortness of breath                                                                                                                                                             | <input type="checkbox"/>                                                                            |
| Difficulty breathing                                                                                                                                                            | <input type="checkbox"/>                                                                            |
| Fatigue                                                                                                                                                                         | <input type="checkbox"/>                                                                            |
| Muscle aches                                                                                                                                                                    | <input type="checkbox"/>                                                                            |
| Body aches                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Headache                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| New loss of taste                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| New loss of smell                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| Sore throat                                                                                                                                                                     | <input type="checkbox"/>                                                                            |
| Congestion                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Runny nose                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Nausea                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Vomiting                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Diarrhea                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?                                        | No <input type="radio"/><br>Yes <input type="radio"/>                                               |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

15 NOV 2020 23:59

US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:04

**TIMEPOINT**

DAY 82

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission

22 NOV 2020 23:06:07

Patient Cloud Open Date & Time

18 NOV 2020 00:01

Patient Cloud Close Date & Time

22 NOV 2020 23:59

US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:04

| TIMEPOINT                                                                                                                                                                       | DAY 89                                                                                              |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):                                                                           |                                                                                                     |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )                                                                                                            | <input type="checkbox"/>                                                                            |
| Chills                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Cough                                                                                                                                                                           | <input type="checkbox"/>                                                                            |
| Shortness of breath                                                                                                                                                             | <input type="checkbox"/>                                                                            |
| Difficulty breathing                                                                                                                                                            | <input type="checkbox"/>                                                                            |
| Fatigue                                                                                                                                                                         | <input type="checkbox"/>                                                                            |
| Muscle aches                                                                                                                                                                    | <input type="checkbox"/>                                                                            |
| Body aches                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Headache                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| New loss of taste                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| New loss of smell                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| Sore throat                                                                                                                                                                     | <input type="checkbox"/>                                                                            |
| Congestion                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Runny nose                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Nausea                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Vomiting                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Diarrhea                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?                                        | No <input type="radio"/><br>Yes <input type="radio"/>                                               |



**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

29 NOV 2020 23:59

US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:04

| TIMEPOINT                                                                                                                                                                       | DAY 96                                                                                              |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):                                                                           |                                                                                                     |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )                                                                                                            | <input type="checkbox"/>                                                                            |
| Chills                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Cough                                                                                                                                                                           | <input type="checkbox"/>                                                                            |
| Shortness of breath                                                                                                                                                             | <input type="checkbox"/>                                                                            |
| Difficulty breathing                                                                                                                                                            | <input type="checkbox"/>                                                                            |
| Fatigue                                                                                                                                                                         | <input type="checkbox"/>                                                                            |
| Muscle aches                                                                                                                                                                    | <input type="checkbox"/>                                                                            |
| Body aches                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Headache                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| New loss of taste                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| New loss of smell                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| Sore throat                                                                                                                                                                     | <input type="checkbox"/>                                                                            |
| Congestion                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Runny nose                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Nausea                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Vomiting                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Diarrhea                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?                                        | No <input type="radio"/><br>Yes <input type="radio"/>                                               |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

06 DEC 2020 23:59

US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:04

| TIMEPOINT                                                                                                                                                                       | DAY 103                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):                                                                           |                                                                                                     |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )                                                                                                            | <input type="checkbox"/>                                                                            |
| Chills                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Cough                                                                                                                                                                           | <input type="checkbox"/>                                                                            |
| Shortness of breath                                                                                                                                                             | <input type="checkbox"/>                                                                            |
| Difficulty breathing                                                                                                                                                            | <input type="checkbox"/>                                                                            |
| Fatigue                                                                                                                                                                         | <input type="checkbox"/>                                                                            |
| Muscle aches                                                                                                                                                                    | <input type="checkbox"/>                                                                            |
| Body aches                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Headache                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| New loss of taste                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| New loss of smell                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| Sore throat                                                                                                                                                                     | <input type="checkbox"/>                                                                            |
| Congestion                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Runny nose                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Nausea                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Vomiting                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Diarrhea                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?                                        | No <input type="radio"/><br>Yes <input type="radio"/>                                               |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

13 DEC 2020 23:59

US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:04

| TIMEPOINT                                                                                                                                                                       | DAY 110                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):                                                                           |                                                                                                     |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )                                                                                                            | <input type="checkbox"/>                                                                            |
| Chills                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Cough                                                                                                                                                                           | <input type="checkbox"/>                                                                            |
| Shortness of breath                                                                                                                                                             | <input type="checkbox"/>                                                                            |
| Difficulty breathing                                                                                                                                                            | <input type="checkbox"/>                                                                            |
| Fatigue                                                                                                                                                                         | <input type="checkbox"/>                                                                            |
| Muscle aches                                                                                                                                                                    | <input type="checkbox"/>                                                                            |
| Body aches                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Headache                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| New loss of taste                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| New loss of smell                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| Sore throat                                                                                                                                                                     | <input type="checkbox"/>                                                                            |
| Congestion                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Runny nose                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Nausea                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Vomiting                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Diarrhea                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?                                        | No <input type="radio"/><br>Yes <input type="radio"/>                                               |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

20 DEC 2020 23:59

US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:04

| TIMEPOINT                                                                                                                                                                       | DAY 117                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):                                                                           |                                                                                                     |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )                                                                                                            | <input type="checkbox"/>                                                                            |
| Chills                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Cough                                                                                                                                                                           | <input type="checkbox"/>                                                                            |
| Shortness of breath                                                                                                                                                             | <input type="checkbox"/>                                                                            |
| Difficulty breathing                                                                                                                                                            | <input type="checkbox"/>                                                                            |
| Fatigue                                                                                                                                                                         | <input type="checkbox"/>                                                                            |
| Muscle aches                                                                                                                                                                    | <input type="checkbox"/>                                                                            |
| Body aches                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Headache                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| New loss of taste                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| New loss of smell                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| Sore throat                                                                                                                                                                     | <input type="checkbox"/>                                                                            |
| Congestion                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Runny nose                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Nausea                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Vomiting                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Diarrhea                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?                                        | No <input type="radio"/><br>Yes <input type="radio"/>                                               |



**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

27 DEC 2020 23:59

US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:04

| TIMEPOINT                                                                                                                                                                       | DAY 124                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):                                                                           |                                                                                                     |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )                                                                                                            | <input type="checkbox"/>                                                                            |
| Chills                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Cough                                                                                                                                                                           | <input type="checkbox"/>                                                                            |
| Shortness of breath                                                                                                                                                             | <input type="checkbox"/>                                                                            |
| Difficulty breathing                                                                                                                                                            | <input type="checkbox"/>                                                                            |
| Fatigue                                                                                                                                                                         | <input type="checkbox"/>                                                                            |
| Muscle aches                                                                                                                                                                    | <input type="checkbox"/>                                                                            |
| Body aches                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Headache                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| New loss of taste                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| New loss of smell                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| Sore throat                                                                                                                                                                     | <input type="checkbox"/>                                                                            |
| Congestion                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Runny nose                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Nausea                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Vomiting                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Diarrhea                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?                                        | No <input type="radio"/><br>Yes <input type="radio"/>                                               |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

03 JAN 2021 23:59

US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:04

| TIMEPOINT                                                                                                                                                                       | DAY 131                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):                                                                           |                                                                                                     |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )                                                                                                            | <input type="checkbox"/>                                                                            |
| Chills                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Cough                                                                                                                                                                           | <input type="checkbox"/>                                                                            |
| Shortness of breath                                                                                                                                                             | <input type="checkbox"/>                                                                            |
| Difficulty breathing                                                                                                                                                            | <input type="checkbox"/>                                                                            |
| Fatigue                                                                                                                                                                         | <input type="checkbox"/>                                                                            |
| Muscle aches                                                                                                                                                                    | <input type="checkbox"/>                                                                            |
| Body aches                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Headache                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| New loss of taste                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| New loss of smell                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| Sore throat                                                                                                                                                                     | <input type="checkbox"/>                                                                            |
| Congestion                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Runny nose                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Nausea                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Vomiting                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Diarrhea                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?                                        | No <input type="radio"/><br>Yes <input type="radio"/>                                               |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

10 JAN 2021 23:59

US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:04

| TIMEPOINT                                                                                                                                                                       | DAY 138                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):                                                                           |                                                                                                     |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )                                                                                                            | <input type="checkbox"/>                                                                            |
| Chills                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Cough                                                                                                                                                                           | <input type="checkbox"/>                                                                            |
| Shortness of breath                                                                                                                                                             | <input type="checkbox"/>                                                                            |
| Difficulty breathing                                                                                                                                                            | <input type="checkbox"/>                                                                            |
| Fatigue                                                                                                                                                                         | <input type="checkbox"/>                                                                            |
| Muscle aches                                                                                                                                                                    | <input type="checkbox"/>                                                                            |
| Body aches                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Headache                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| New loss of taste                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| New loss of smell                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| Sore throat                                                                                                                                                                     | <input type="checkbox"/>                                                                            |
| Congestion                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Runny nose                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Nausea                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Vomiting                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Diarrhea                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?                                        | No <input type="radio"/><br>Yes <input type="radio"/>                                               |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

17 JAN 2021 23:59

US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:04

| TIMEPOINT                                                                                                                                                                       | DAY 145                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):                                                                           |                                                                                                     |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )                                                                                                            | <input type="checkbox"/>                                                                            |
| Chills                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Cough                                                                                                                                                                           | <input type="checkbox"/>                                                                            |
| Shortness of breath                                                                                                                                                             | <input type="checkbox"/>                                                                            |
| Difficulty breathing                                                                                                                                                            | <input type="checkbox"/>                                                                            |
| Fatigue                                                                                                                                                                         | <input type="checkbox"/>                                                                            |
| Muscle aches                                                                                                                                                                    | <input type="checkbox"/>                                                                            |
| Body aches                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Headache                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| New loss of taste                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| New loss of smell                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| Sore throat                                                                                                                                                                     | <input type="checkbox"/>                                                                            |
| Congestion                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Runny nose                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Nausea                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Vomiting                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Diarrhea                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?                                        | No <input type="radio"/><br>Yes <input type="radio"/>                                               |



**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

24 JAN 2021 23:59

US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:04

| TIMEPOINT                                                                                                                                                                       | DAY 152                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):                                                                           |                                                                                                     |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )                                                                                                            | <input type="checkbox"/>                                                                            |
| Chills                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Cough                                                                                                                                                                           | <input type="checkbox"/>                                                                            |
| Shortness of breath                                                                                                                                                             | <input type="checkbox"/>                                                                            |
| Difficulty breathing                                                                                                                                                            | <input type="checkbox"/>                                                                            |
| Fatigue                                                                                                                                                                         | <input type="checkbox"/>                                                                            |
| Muscle aches                                                                                                                                                                    | <input type="checkbox"/>                                                                            |
| Body aches                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Headache                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| New loss of taste                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| New loss of smell                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| Sore throat                                                                                                                                                                     | <input type="checkbox"/>                                                                            |
| Congestion                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Runny nose                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Nausea                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Vomiting                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Diarrhea                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?                                        | No <input type="radio"/><br>Yes <input type="radio"/>                                               |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

31 JAN 2021 23:59

US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:04

**TIMEPOINT**

DAY 159

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

07 FEB 2021 23:59

US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:04

| TIMEPOINT                                                                                                                                                                       | DAY 166                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):                                                                           |                                                                                                     |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )                                                                                                            | <input type="checkbox"/>                                                                            |
| Chills                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Cough                                                                                                                                                                           | <input type="checkbox"/>                                                                            |
| Shortness of breath                                                                                                                                                             | <input type="checkbox"/>                                                                            |
| Difficulty breathing                                                                                                                                                            | <input type="checkbox"/>                                                                            |
| Fatigue                                                                                                                                                                         | <input type="checkbox"/>                                                                            |
| Muscle aches                                                                                                                                                                    | <input type="checkbox"/>                                                                            |
| Body aches                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Headache                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| New loss of taste                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| New loss of smell                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| Sore throat                                                                                                                                                                     | <input type="checkbox"/>                                                                            |
| Congestion                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Runny nose                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Nausea                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Vomiting                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Diarrhea                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?                                        | No <input type="radio"/><br>Yes <input type="radio"/>                                               |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

14 FEB 2021 23:59

US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:04

| TIMEPOINT                                                                                                                                                                       | DAY 173                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):                                                                           |                                                                                                     |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )                                                                                                            | <input type="checkbox"/>                                                                            |
| Chills                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Cough                                                                                                                                                                           | <input type="checkbox"/>                                                                            |
| Shortness of breath                                                                                                                                                             | <input type="checkbox"/>                                                                            |
| Difficulty breathing                                                                                                                                                            | <input type="checkbox"/>                                                                            |
| Fatigue                                                                                                                                                                         | <input type="checkbox"/>                                                                            |
| Muscle aches                                                                                                                                                                    | <input type="checkbox"/>                                                                            |
| Body aches                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Headache                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| New loss of taste                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| New loss of smell                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| Sore throat                                                                                                                                                                     | <input type="checkbox"/>                                                                            |
| Congestion                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Runny nose                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Nausea                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Vomiting                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Diarrhea                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?                                        | No <input type="radio"/><br>Yes <input type="radio"/>                                               |



**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

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Date and time of submission

[Patient Cloud Open Date & Time](#)

17 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

21 FEB 2021 23:59

US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:04

| TIMEPOINT                                                                                                                                                                       | DAY 180                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):                                                                           |                                                                                                     |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )                                                                                                            | <input type="checkbox"/>                                                                            |
| Chills                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Cough                                                                                                                                                                           | <input type="checkbox"/>                                                                            |
| Shortness of breath                                                                                                                                                             | <input type="checkbox"/>                                                                            |
| Difficulty breathing                                                                                                                                                            | <input type="checkbox"/>                                                                            |
| Fatigue                                                                                                                                                                         | <input type="checkbox"/>                                                                            |
| Muscle aches                                                                                                                                                                    | <input type="checkbox"/>                                                                            |
| Body aches                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Headache                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| New loss of taste                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| New loss of smell                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| Sore throat                                                                                                                                                                     | <input type="checkbox"/>                                                                            |
| Congestion                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Runny nose                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Nausea                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Vomiting                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Diarrhea                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?                                        | No <input type="radio"/><br>Yes <input type="radio"/>                                               |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

28 FEB 2021 23:59

US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:04

| TIMEPOINT                                                                                                                                                                       | DAY 187                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):                                                                           |                                                                                                     |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )                                                                                                            | <input type="checkbox"/>                                                                            |
| Chills                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Cough                                                                                                                                                                           | <input type="checkbox"/>                                                                            |
| Shortness of breath                                                                                                                                                             | <input type="checkbox"/>                                                                            |
| Difficulty breathing                                                                                                                                                            | <input type="checkbox"/>                                                                            |
| Fatigue                                                                                                                                                                         | <input type="checkbox"/>                                                                            |
| Muscle aches                                                                                                                                                                    | <input type="checkbox"/>                                                                            |
| Body aches                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Headache                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| New loss of taste                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| New loss of smell                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| Sore throat                                                                                                                                                                     | <input type="checkbox"/>                                                                            |
| Congestion                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Runny nose                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Nausea                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Vomiting                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Diarrhea                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?                                        | No <input type="radio"/><br>Yes <input type="radio"/>                                               |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

07 MAR 2021 23:59

US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:04

| TIMEPOINT                                                                                                                                                                       | DAY 194                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):                                                                           |                                                                                                     |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )                                                                                                            | <input type="checkbox"/>                                                                            |
| Chills                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Cough                                                                                                                                                                           | <input type="checkbox"/>                                                                            |
| Shortness of breath                                                                                                                                                             | <input type="checkbox"/>                                                                            |
| Difficulty breathing                                                                                                                                                            | <input type="checkbox"/>                                                                            |
| Fatigue                                                                                                                                                                         | <input type="checkbox"/>                                                                            |
| Muscle aches                                                                                                                                                                    | <input type="checkbox"/>                                                                            |
| Body aches                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Headache                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| New loss of taste                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| New loss of smell                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| Sore throat                                                                                                                                                                     | <input type="checkbox"/>                                                                            |
| Congestion                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Runny nose                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Nausea                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Vomiting                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Diarrhea                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?                                        | No <input type="radio"/><br>Yes <input type="radio"/>                                               |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

14 MAR 2021 23:59

US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:04

| TIMEPOINT                                                                                                                                                                       | DAY 201                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):                                                                           |                                                                                                     |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )                                                                                                            | <input type="checkbox"/>                                                                            |
| Chills                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Cough                                                                                                                                                                           | <input type="checkbox"/>                                                                            |
| Shortness of breath                                                                                                                                                             | <input type="checkbox"/>                                                                            |
| Difficulty breathing                                                                                                                                                            | <input type="checkbox"/>                                                                            |
| Fatigue                                                                                                                                                                         | <input type="checkbox"/>                                                                            |
| Muscle aches                                                                                                                                                                    | <input type="checkbox"/>                                                                            |
| Body aches                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Headache                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| New loss of taste                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| New loss of smell                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| Sore throat                                                                                                                                                                     | <input type="checkbox"/>                                                                            |
| Congestion                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Runny nose                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Nausea                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Vomiting                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Diarrhea                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?                                        | No <input type="radio"/><br>Yes <input type="radio"/>                                               |



**US3742169**

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I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

21 MAR 2021 23:59

US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:04

| TIMEPOINT                                                                                                                                                                       | DAY 208                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):                                                                           |                                                                                                     |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )                                                                                                            | <input type="checkbox"/>                                                                            |
| Chills                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Cough                                                                                                                                                                           | <input type="checkbox"/>                                                                            |
| Shortness of breath                                                                                                                                                             | <input type="checkbox"/>                                                                            |
| Difficulty breathing                                                                                                                                                            | <input type="checkbox"/>                                                                            |
| Fatigue                                                                                                                                                                         | <input type="checkbox"/>                                                                            |
| Muscle aches                                                                                                                                                                    | <input type="checkbox"/>                                                                            |
| Body aches                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Headache                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| New loss of taste                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| New loss of smell                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| Sore throat                                                                                                                                                                     | <input type="checkbox"/>                                                                            |
| Congestion                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Runny nose                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Nausea                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Vomiting                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Diarrhea                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?                                        | No <input type="radio"/><br>Yes <input type="radio"/>                                               |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

28 MAR 2021 23:59

US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:04

| TIMEPOINT                                                                                                                                                                       | DAY 215                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):                                                                           |                                                                                                     |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )                                                                                                            | <input type="checkbox"/>                                                                            |
| Chills                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Cough                                                                                                                                                                           | <input type="checkbox"/>                                                                            |
| Shortness of breath                                                                                                                                                             | <input type="checkbox"/>                                                                            |
| Difficulty breathing                                                                                                                                                            | <input type="checkbox"/>                                                                            |
| Fatigue                                                                                                                                                                         | <input type="checkbox"/>                                                                            |
| Muscle aches                                                                                                                                                                    | <input type="checkbox"/>                                                                            |
| Body aches                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Headache                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| New loss of taste                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| New loss of smell                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| Sore throat                                                                                                                                                                     | <input type="checkbox"/>                                                                            |
| Congestion                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Runny nose                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Nausea                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Vomiting                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Diarrhea                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?                                        | No <input type="radio"/><br>Yes <input type="radio"/>                                               |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

04 APR 2021 23:59

US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:04

| TIMEPOINT                                                                                                                                                                       | DAY 222                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):                                                                           |                                                                                                     |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )                                                                                                            | <input type="checkbox"/>                                                                            |
| Chills                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Cough                                                                                                                                                                           | <input type="checkbox"/>                                                                            |
| Shortness of breath                                                                                                                                                             | <input type="checkbox"/>                                                                            |
| Difficulty breathing                                                                                                                                                            | <input type="checkbox"/>                                                                            |
| Fatigue                                                                                                                                                                         | <input type="checkbox"/>                                                                            |
| Muscle aches                                                                                                                                                                    | <input type="checkbox"/>                                                                            |
| Body aches                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Headache                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| New loss of taste                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| New loss of smell                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| Sore throat                                                                                                                                                                     | <input type="checkbox"/>                                                                            |
| Congestion                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Runny nose                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Nausea                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Vomiting                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Diarrhea                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?                                        | No <input type="radio"/><br>Yes <input type="radio"/>                                               |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

11 APR 2021 23:59

US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:04

| TIMEPOINT                                                                                                                                                                       | DAY 229                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):                                                                           |                                                                                                     |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )                                                                                                            | <input type="checkbox"/>                                                                            |
| Chills                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Cough                                                                                                                                                                           | <input type="checkbox"/>                                                                            |
| Shortness of breath                                                                                                                                                             | <input type="checkbox"/>                                                                            |
| Difficulty breathing                                                                                                                                                            | <input type="checkbox"/>                                                                            |
| Fatigue                                                                                                                                                                         | <input type="checkbox"/>                                                                            |
| Muscle aches                                                                                                                                                                    | <input type="checkbox"/>                                                                            |
| Body aches                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Headache                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| New loss of taste                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| New loss of smell                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| Sore throat                                                                                                                                                                     | <input type="checkbox"/>                                                                            |
| Congestion                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Runny nose                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Nausea                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Vomiting                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Diarrhea                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?                                        | No <input type="radio"/><br>Yes <input type="radio"/>                                               |



**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

18 APR 2021 23:59

US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:04

| TIMEPOINT                                                                                                                                                                       | DAY 236                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):                                                                           |                                                                                                     |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )                                                                                                            | <input type="checkbox"/>                                                                            |
| Chills                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Cough                                                                                                                                                                           | <input type="checkbox"/>                                                                            |
| Shortness of breath                                                                                                                                                             | <input type="checkbox"/>                                                                            |
| Difficulty breathing                                                                                                                                                            | <input type="checkbox"/>                                                                            |
| Fatigue                                                                                                                                                                         | <input type="checkbox"/>                                                                            |
| Muscle aches                                                                                                                                                                    | <input type="checkbox"/>                                                                            |
| Body aches                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Headache                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| New loss of taste                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| New loss of smell                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| Sore throat                                                                                                                                                                     | <input type="checkbox"/>                                                                            |
| Congestion                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Runny nose                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Nausea                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Vomiting                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Diarrhea                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?                                        | No <input type="radio"/><br>Yes <input type="radio"/>                                               |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

25 APR 2021 23:59

US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:04

| TIMEPOINT                                                                                                                                                                       | DAY 243                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):                                                                           |                                                                                                     |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )                                                                                                            | <input type="checkbox"/>                                                                            |
| Chills                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Cough                                                                                                                                                                           | <input type="checkbox"/>                                                                            |
| Shortness of breath                                                                                                                                                             | <input type="checkbox"/>                                                                            |
| Difficulty breathing                                                                                                                                                            | <input type="checkbox"/>                                                                            |
| Fatigue                                                                                                                                                                         | <input type="checkbox"/>                                                                            |
| Muscle aches                                                                                                                                                                    | <input type="checkbox"/>                                                                            |
| Body aches                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Headache                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| New loss of taste                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| New loss of smell                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| Sore throat                                                                                                                                                                     | <input type="checkbox"/>                                                                            |
| Congestion                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Runny nose                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Nausea                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Vomiting                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Diarrhea                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?                                        | No <input type="radio"/><br>Yes <input type="radio"/>                                               |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

02 MAY 2021 23:59

US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:04

| TIMEPOINT                                                                                                                                                                       | DAY 250                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):                                                                           |                                                                                                     |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )                                                                                                            | <input type="checkbox"/>                                                                            |
| Chills                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Cough                                                                                                                                                                           | <input type="checkbox"/>                                                                            |
| Shortness of breath                                                                                                                                                             | <input type="checkbox"/>                                                                            |
| Difficulty breathing                                                                                                                                                            | <input type="checkbox"/>                                                                            |
| Fatigue                                                                                                                                                                         | <input type="checkbox"/>                                                                            |
| Muscle aches                                                                                                                                                                    | <input type="checkbox"/>                                                                            |
| Body aches                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Headache                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| New loss of taste                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| New loss of smell                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| Sore throat                                                                                                                                                                     | <input type="checkbox"/>                                                                            |
| Congestion                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Runny nose                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Nausea                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Vomiting                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Diarrhea                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?                                        | No <input type="radio"/><br>Yes <input type="radio"/>                                               |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

09 MAY 2021 23:59

US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:04

| TIMEPOINT                                                                                                                                                                       | DAY 257                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):                                                                           |                                                                                                     |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )                                                                                                            | <input type="checkbox"/>                                                                            |
| Chills                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Cough                                                                                                                                                                           | <input type="checkbox"/>                                                                            |
| Shortness of breath                                                                                                                                                             | <input type="checkbox"/>                                                                            |
| Difficulty breathing                                                                                                                                                            | <input type="checkbox"/>                                                                            |
| Fatigue                                                                                                                                                                         | <input type="checkbox"/>                                                                            |
| Muscle aches                                                                                                                                                                    | <input type="checkbox"/>                                                                            |
| Body aches                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Headache                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| New loss of taste                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| New loss of smell                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| Sore throat                                                                                                                                                                     | <input type="checkbox"/>                                                                            |
| Congestion                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Runny nose                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Nausea                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Vomiting                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Diarrhea                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?                                        | No <input type="radio"/><br>Yes <input type="radio"/>                                               |



**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

16 MAY 2021 23:59

US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:04

| TIMEPOINT                                                                                                                                                                       | DAY 264                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):                                                                           |                                                                                                     |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )                                                                                                            | <input type="checkbox"/>                                                                            |
| Chills                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Cough                                                                                                                                                                           | <input type="checkbox"/>                                                                            |
| Shortness of breath                                                                                                                                                             | <input type="checkbox"/>                                                                            |
| Difficulty breathing                                                                                                                                                            | <input type="checkbox"/>                                                                            |
| Fatigue                                                                                                                                                                         | <input type="checkbox"/>                                                                            |
| Muscle aches                                                                                                                                                                    | <input type="checkbox"/>                                                                            |
| Body aches                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Headache                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| New loss of taste                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| New loss of smell                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| Sore throat                                                                                                                                                                     | <input type="checkbox"/>                                                                            |
| Congestion                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Runny nose                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Nausea                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Vomiting                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Diarrhea                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?                                        | No <input type="radio"/><br>Yes <input type="radio"/>                                               |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

23 MAY 2021 23:59

US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:04

| TIMEPOINT                                                                                                                                                                       | DAY 271                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):                                                                           |                                                                                                     |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )                                                                                                            | <input type="checkbox"/>                                                                            |
| Chills                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Cough                                                                                                                                                                           | <input type="checkbox"/>                                                                            |
| Shortness of breath                                                                                                                                                             | <input type="checkbox"/>                                                                            |
| Difficulty breathing                                                                                                                                                            | <input type="checkbox"/>                                                                            |
| Fatigue                                                                                                                                                                         | <input type="checkbox"/>                                                                            |
| Muscle aches                                                                                                                                                                    | <input type="checkbox"/>                                                                            |
| Body aches                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Headache                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| New loss of taste                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| New loss of smell                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| Sore throat                                                                                                                                                                     | <input type="checkbox"/>                                                                            |
| Congestion                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Runny nose                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Nausea                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Vomiting                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Diarrhea                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?                                        | No <input type="radio"/><br>Yes <input type="radio"/>                                               |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

30 MAY 2021 23:59

US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:04

| TIMEPOINT                                                                                                                                                                       | DAY 278                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):                                                                           |                                                                                                     |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )                                                                                                            | <input type="checkbox"/>                                                                            |
| Chills                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Cough                                                                                                                                                                           | <input type="checkbox"/>                                                                            |
| Shortness of breath                                                                                                                                                             | <input type="checkbox"/>                                                                            |
| Difficulty breathing                                                                                                                                                            | <input type="checkbox"/>                                                                            |
| Fatigue                                                                                                                                                                         | <input type="checkbox"/>                                                                            |
| Muscle aches                                                                                                                                                                    | <input type="checkbox"/>                                                                            |
| Body aches                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Headache                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| New loss of taste                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| New loss of smell                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| Sore throat                                                                                                                                                                     | <input type="checkbox"/>                                                                            |
| Congestion                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Runny nose                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Nausea                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Vomiting                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Diarrhea                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?                                        | No <input type="radio"/><br>Yes <input type="radio"/>                                               |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

06 JUN 2021 23:59

US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:04

| TIMEPOINT                                                                                                                                                                       | DAY 285                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):                                                                           |                                                                                                     |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )                                                                                                            | <input type="checkbox"/>                                                                            |
| Chills                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Cough                                                                                                                                                                           | <input type="checkbox"/>                                                                            |
| Shortness of breath                                                                                                                                                             | <input type="checkbox"/>                                                                            |
| Difficulty breathing                                                                                                                                                            | <input type="checkbox"/>                                                                            |
| Fatigue                                                                                                                                                                         | <input type="checkbox"/>                                                                            |
| Muscle aches                                                                                                                                                                    | <input type="checkbox"/>                                                                            |
| Body aches                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Headache                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| New loss of taste                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| New loss of smell                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| Sore throat                                                                                                                                                                     | <input type="checkbox"/>                                                                            |
| Congestion                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Runny nose                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Nausea                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Vomiting                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Diarrhea                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?                                        | No <input type="radio"/><br>Yes <input type="radio"/>                                               |



**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

13 JUN 2021 23:59

US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:04

| TIMEPOINT                                                                                                                                                                       | DAY 292                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):                                                                           |                                                                                                     |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )                                                                                                            | <input type="checkbox"/>                                                                            |
| Chills                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Cough                                                                                                                                                                           | <input type="checkbox"/>                                                                            |
| Shortness of breath                                                                                                                                                             | <input type="checkbox"/>                                                                            |
| Difficulty breathing                                                                                                                                                            | <input type="checkbox"/>                                                                            |
| Fatigue                                                                                                                                                                         | <input type="checkbox"/>                                                                            |
| Muscle aches                                                                                                                                                                    | <input type="checkbox"/>                                                                            |
| Body aches                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Headache                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| New loss of taste                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| New loss of smell                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| Sore throat                                                                                                                                                                     | <input type="checkbox"/>                                                                            |
| Congestion                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Runny nose                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Nausea                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Vomiting                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Diarrhea                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?                                        | No <input type="radio"/><br>Yes <input type="radio"/>                                               |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

20 JUN 2021 23:59

US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:04

| TIMEPOINT                                                                                                                                                                       | DAY 299                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):                                                                           |                                                                                                     |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )                                                                                                            | <input type="checkbox"/>                                                                            |
| Chills                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Cough                                                                                                                                                                           | <input type="checkbox"/>                                                                            |
| Shortness of breath                                                                                                                                                             | <input type="checkbox"/>                                                                            |
| Difficulty breathing                                                                                                                                                            | <input type="checkbox"/>                                                                            |
| Fatigue                                                                                                                                                                         | <input type="checkbox"/>                                                                            |
| Muscle aches                                                                                                                                                                    | <input type="checkbox"/>                                                                            |
| Body aches                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Headache                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| New loss of taste                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| New loss of smell                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| Sore throat                                                                                                                                                                     | <input type="checkbox"/>                                                                            |
| Congestion                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Runny nose                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Nausea                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Vomiting                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Diarrhea                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?                                        | No <input type="radio"/><br>Yes <input type="radio"/>                                               |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

27 JUN 2021 23:59

US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:04

**TIMEPOINT**

DAY 306

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

04 JUL 2021 23:59

US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:04

| TIMEPOINT                                                                                                                                                                       | DAY 313                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):                                                                           |                                                                                                     |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )                                                                                                            | <input type="checkbox"/>                                                                            |
| Chills                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Cough                                                                                                                                                                           | <input type="checkbox"/>                                                                            |
| Shortness of breath                                                                                                                                                             | <input type="checkbox"/>                                                                            |
| Difficulty breathing                                                                                                                                                            | <input type="checkbox"/>                                                                            |
| Fatigue                                                                                                                                                                         | <input type="checkbox"/>                                                                            |
| Muscle aches                                                                                                                                                                    | <input type="checkbox"/>                                                                            |
| Body aches                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Headache                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| New loss of taste                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| New loss of smell                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| Sore throat                                                                                                                                                                     | <input type="checkbox"/>                                                                            |
| Congestion                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Runny nose                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Nausea                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Vomiting                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Diarrhea                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?                                        | No <input type="radio"/><br>Yes <input type="radio"/>                                               |



**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

11 JUL 2021 23:59

US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:04

| TIMEPOINT                                                                                                                                                                       | DAY 320                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):                                                                           |                                                                                                     |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )                                                                                                            | <input type="checkbox"/>                                                                            |
| Chills                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Cough                                                                                                                                                                           | <input type="checkbox"/>                                                                            |
| Shortness of breath                                                                                                                                                             | <input type="checkbox"/>                                                                            |
| Difficulty breathing                                                                                                                                                            | <input type="checkbox"/>                                                                            |
| Fatigue                                                                                                                                                                         | <input type="checkbox"/>                                                                            |
| Muscle aches                                                                                                                                                                    | <input type="checkbox"/>                                                                            |
| Body aches                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Headache                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| New loss of taste                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| New loss of smell                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| Sore throat                                                                                                                                                                     | <input type="checkbox"/>                                                                            |
| Congestion                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Runny nose                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Nausea                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Vomiting                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Diarrhea                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?                                        | No <input type="radio"/><br>Yes <input type="radio"/>                                               |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

18 JUL 2021 23:59

US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:04

| TIMEPOINT                                                                                                                                                                       | DAY 327                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):                                                                           |                                                                                                     |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )                                                                                                            | <input type="checkbox"/>                                                                            |
| Chills                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Cough                                                                                                                                                                           | <input type="checkbox"/>                                                                            |
| Shortness of breath                                                                                                                                                             | <input type="checkbox"/>                                                                            |
| Difficulty breathing                                                                                                                                                            | <input type="checkbox"/>                                                                            |
| Fatigue                                                                                                                                                                         | <input type="checkbox"/>                                                                            |
| Muscle aches                                                                                                                                                                    | <input type="checkbox"/>                                                                            |
| Body aches                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Headache                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| New loss of taste                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| New loss of smell                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| Sore throat                                                                                                                                                                     | <input type="checkbox"/>                                                                            |
| Congestion                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Runny nose                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Nausea                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Vomiting                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Diarrhea                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?                                        | No <input type="radio"/><br>Yes <input type="radio"/>                                               |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

25 JUL 2021 23:59

US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:04

| TIMEPOINT                                                                                                                                                                       | DAY 334                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):                                                                           |                                                                                                     |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )                                                                                                            | <input type="checkbox"/>                                                                            |
| Chills                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Cough                                                                                                                                                                           | <input type="checkbox"/>                                                                            |
| Shortness of breath                                                                                                                                                             | <input type="checkbox"/>                                                                            |
| Difficulty breathing                                                                                                                                                            | <input type="checkbox"/>                                                                            |
| Fatigue                                                                                                                                                                         | <input type="checkbox"/>                                                                            |
| Muscle aches                                                                                                                                                                    | <input type="checkbox"/>                                                                            |
| Body aches                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Headache                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| New loss of taste                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| New loss of smell                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| Sore throat                                                                                                                                                                     | <input type="checkbox"/>                                                                            |
| Congestion                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Runny nose                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Nausea                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Vomiting                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Diarrhea                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?                                        | No <input type="radio"/><br>Yes <input type="radio"/>                                               |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

01 AUG 2021 23:59

US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:04

| TIMEPOINT                                                                                                                                                                       | DAY 341                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):                                                                           |                                                                                                     |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )                                                                                                            | <input type="checkbox"/>                                                                            |
| Chills                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Cough                                                                                                                                                                           | <input type="checkbox"/>                                                                            |
| Shortness of breath                                                                                                                                                             | <input type="checkbox"/>                                                                            |
| Difficulty breathing                                                                                                                                                            | <input type="checkbox"/>                                                                            |
| Fatigue                                                                                                                                                                         | <input type="checkbox"/>                                                                            |
| Muscle aches                                                                                                                                                                    | <input type="checkbox"/>                                                                            |
| Body aches                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Headache                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| New loss of taste                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| New loss of smell                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| Sore throat                                                                                                                                                                     | <input type="checkbox"/>                                                                            |
| Congestion                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Runny nose                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Nausea                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Vomiting                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Diarrhea                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?                                        | No <input type="radio"/><br>Yes <input type="radio"/>                                               |



**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

08 AUG 2021 23:59

US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:04

| TIMEPOINT                                                                                                                                                                       | DAY 348                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):                                                                           |                                                                                                     |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )                                                                                                            | <input type="checkbox"/>                                                                            |
| Chills                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Cough                                                                                                                                                                           | <input type="checkbox"/>                                                                            |
| Shortness of breath                                                                                                                                                             | <input type="checkbox"/>                                                                            |
| Difficulty breathing                                                                                                                                                            | <input type="checkbox"/>                                                                            |
| Fatigue                                                                                                                                                                         | <input type="checkbox"/>                                                                            |
| Muscle aches                                                                                                                                                                    | <input type="checkbox"/>                                                                            |
| Body aches                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Headache                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| New loss of taste                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| New loss of smell                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| Sore throat                                                                                                                                                                     | <input type="checkbox"/>                                                                            |
| Congestion                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Runny nose                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Nausea                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Vomiting                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Diarrhea                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?                                        | No <input type="radio"/><br>Yes <input type="radio"/>                                               |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

15 AUG 2021 23:59

US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:04

| TIMEPOINT                                                                                                                                                                       | DAY 355                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):                                                                           |                                                                                                     |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )                                                                                                            | <input type="checkbox"/>                                                                            |
| Chills                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Cough                                                                                                                                                                           | <input type="checkbox"/>                                                                            |
| Shortness of breath                                                                                                                                                             | <input type="checkbox"/>                                                                            |
| Difficulty breathing                                                                                                                                                            | <input type="checkbox"/>                                                                            |
| Fatigue                                                                                                                                                                         | <input type="checkbox"/>                                                                            |
| Muscle aches                                                                                                                                                                    | <input type="checkbox"/>                                                                            |
| Body aches                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Headache                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| New loss of taste                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| New loss of smell                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| Sore throat                                                                                                                                                                     | <input type="checkbox"/>                                                                            |
| Congestion                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Runny nose                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Nausea                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Vomiting                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Diarrhea                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?                                        | No <input type="radio"/><br>Yes <input type="radio"/>                                               |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

22 AUG 2021 23:59

US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:04

**TIMEPOINT**

DAY 362

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

29 AUG 2021 23:59

US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:04

**TIMEPOINT**

DAY 369

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐



**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

05 SEP 2021 23:59

US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:04

| TIMEPOINT                                                                                                                                                                       | DAY 376                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):                                                                           |                                                                                                     |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )                                                                                                            | <input type="checkbox"/>                                                                            |
| Chills                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Cough                                                                                                                                                                           | <input type="checkbox"/>                                                                            |
| Shortness of breath                                                                                                                                                             | <input type="checkbox"/>                                                                            |
| Difficulty breathing                                                                                                                                                            | <input type="checkbox"/>                                                                            |
| Fatigue                                                                                                                                                                         | <input type="checkbox"/>                                                                            |
| Muscle aches                                                                                                                                                                    | <input type="checkbox"/>                                                                            |
| Body aches                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Headache                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| New loss of taste                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| New loss of smell                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| Sore throat                                                                                                                                                                     | <input type="checkbox"/>                                                                            |
| Congestion                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Runny nose                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Nausea                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Vomiting                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Diarrhea                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?                                        | No <input type="radio"/><br>Yes <input type="radio"/>                                               |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

12 SEP 2021 23:59

US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:04

TIMEPOINT

DAY 383

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

19 SEP 2021 23:59

US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:04

| TIMEPOINT                                                                                                                                                                       | DAY 390                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):                                                                           |                                                                                                     |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )                                                                                                            | <input type="checkbox"/>                                                                            |
| Chills                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Cough                                                                                                                                                                           | <input type="checkbox"/>                                                                            |
| Shortness of breath                                                                                                                                                             | <input type="checkbox"/>                                                                            |
| Difficulty breathing                                                                                                                                                            | <input type="checkbox"/>                                                                            |
| Fatigue                                                                                                                                                                         | <input type="checkbox"/>                                                                            |
| Muscle aches                                                                                                                                                                    | <input type="checkbox"/>                                                                            |
| Body aches                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Headache                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| New loss of taste                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| New loss of smell                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| Sore throat                                                                                                                                                                     | <input type="checkbox"/>                                                                            |
| Congestion                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Runny nose                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Nausea                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Vomiting                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Diarrhea                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?                                        | No <input type="radio"/><br>Yes <input type="radio"/>                                               |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

26 SEP 2021 23:59

US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:04

| TIMEPOINT                                                                                                                                                                       | DAY 397                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):                                                                           |                                                                                                     |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )                                                                                                            | <input type="checkbox"/>                                                                            |
| Chills                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Cough                                                                                                                                                                           | <input type="checkbox"/>                                                                            |
| Shortness of breath                                                                                                                                                             | <input type="checkbox"/>                                                                            |
| Difficulty breathing                                                                                                                                                            | <input type="checkbox"/>                                                                            |
| Fatigue                                                                                                                                                                         | <input type="checkbox"/>                                                                            |
| Muscle aches                                                                                                                                                                    | <input type="checkbox"/>                                                                            |
| Body aches                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Headache                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| New loss of taste                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| New loss of smell                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| Sore throat                                                                                                                                                                     | <input type="checkbox"/>                                                                            |
| Congestion                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Runny nose                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Nausea                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Vomiting                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Diarrhea                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?                                        | No <input type="radio"/><br>Yes <input type="radio"/>                                               |



**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

03 OCT 2021 23:59

US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:04

| TIMEPOINT                                                                                                                                                                       | DAY 404                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):                                                                           |                                                                                                     |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )                                                                                                            | <input type="checkbox"/>                                                                            |
| Chills                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Cough                                                                                                                                                                           | <input type="checkbox"/>                                                                            |
| Shortness of breath                                                                                                                                                             | <input type="checkbox"/>                                                                            |
| Difficulty breathing                                                                                                                                                            | <input type="checkbox"/>                                                                            |
| Fatigue                                                                                                                                                                         | <input type="checkbox"/>                                                                            |
| Muscle aches                                                                                                                                                                    | <input type="checkbox"/>                                                                            |
| Body aches                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Headache                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| New loss of taste                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| New loss of smell                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| Sore throat                                                                                                                                                                     | <input type="checkbox"/>                                                                            |
| Congestion                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Runny nose                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Nausea                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Vomiting                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Diarrhea                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?                                        | No <input type="radio"/><br>Yes <input type="radio"/>                                               |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

10 OCT 2021 23:59

US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:04

| TIMEPOINT                                                                                                                                                                       | DAY 411                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):                                                                           |                                                                                                     |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )                                                                                                            | <input type="checkbox"/>                                                                            |
| Chills                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Cough                                                                                                                                                                           | <input type="checkbox"/>                                                                            |
| Shortness of breath                                                                                                                                                             | <input type="checkbox"/>                                                                            |
| Difficulty breathing                                                                                                                                                            | <input type="checkbox"/>                                                                            |
| Fatigue                                                                                                                                                                         | <input type="checkbox"/>                                                                            |
| Muscle aches                                                                                                                                                                    | <input type="checkbox"/>                                                                            |
| Body aches                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Headache                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| New loss of taste                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| New loss of smell                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| Sore throat                                                                                                                                                                     | <input type="checkbox"/>                                                                            |
| Congestion                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Runny nose                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Nausea                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Vomiting                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Diarrhea                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?                                        | No <input type="radio"/><br>Yes <input type="radio"/>                                               |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

17 OCT 2021 23:59

US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:04

**TIMEPOINT**

DAY 418

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

24 OCT 2021 23:59

US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:04

TIMEPOINT

DAY 425

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐



**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

31 OCT 2021 23:59

US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:04

**TIMEPOINT**

DAY 432

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

07 NOV 2021 23:59

US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:04

| TIMEPOINT                                                                                                                                                                       | DAY 439                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):                                                                           |                                                                                                     |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )                                                                                                            | <input type="checkbox"/>                                                                            |
| Chills                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Cough                                                                                                                                                                           | <input type="checkbox"/>                                                                            |
| Shortness of breath                                                                                                                                                             | <input type="checkbox"/>                                                                            |
| Difficulty breathing                                                                                                                                                            | <input type="checkbox"/>                                                                            |
| Fatigue                                                                                                                                                                         | <input type="checkbox"/>                                                                            |
| Muscle aches                                                                                                                                                                    | <input type="checkbox"/>                                                                            |
| Body aches                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Headache                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| New loss of taste                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| New loss of smell                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| Sore throat                                                                                                                                                                     | <input type="checkbox"/>                                                                            |
| Congestion                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Runny nose                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Nausea                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Vomiting                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Diarrhea                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?                                        | No <input type="radio"/><br>Yes <input type="radio"/>                                               |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

14 NOV 2021 23:59

US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:04

**TIMEPOINT**

DAY 446

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

21 NOV 2021 23:59

US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:04

| TIMEPOINT                                                                                                                                                                       | DAY 453                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):                                                                           |                                                                                                     |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )                                                                                                            | <input type="checkbox"/>                                                                            |
| Chills                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Cough                                                                                                                                                                           | <input type="checkbox"/>                                                                            |
| Shortness of breath                                                                                                                                                             | <input type="checkbox"/>                                                                            |
| Difficulty breathing                                                                                                                                                            | <input type="checkbox"/>                                                                            |
| Fatigue                                                                                                                                                                         | <input type="checkbox"/>                                                                            |
| Muscle aches                                                                                                                                                                    | <input type="checkbox"/>                                                                            |
| Body aches                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Headache                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| New loss of taste                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| New loss of smell                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| Sore throat                                                                                                                                                                     | <input type="checkbox"/>                                                                            |
| Congestion                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Runny nose                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Nausea                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Vomiting                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Diarrhea                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?                                        | No <input type="radio"/><br>Yes <input type="radio"/>                                               |



**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

28 NOV 2021 23:59

US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:04

| TIMEPOINT                                                                                                                                                                       | DAY 460                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):                                                                           |                                                                                                     |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )                                                                                                            | <input type="checkbox"/>                                                                            |
| Chills                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Cough                                                                                                                                                                           | <input type="checkbox"/>                                                                            |
| Shortness of breath                                                                                                                                                             | <input type="checkbox"/>                                                                            |
| Difficulty breathing                                                                                                                                                            | <input type="checkbox"/>                                                                            |
| Fatigue                                                                                                                                                                         | <input type="checkbox"/>                                                                            |
| Muscle aches                                                                                                                                                                    | <input type="checkbox"/>                                                                            |
| Body aches                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Headache                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| New loss of taste                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| New loss of smell                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| Sore throat                                                                                                                                                                     | <input type="checkbox"/>                                                                            |
| Congestion                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Runny nose                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Nausea                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Vomiting                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Diarrhea                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?                                        | No <input type="radio"/><br>Yes <input type="radio"/>                                               |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

05 DEC 2021 23:59

US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:04

| TIMEPOINT                                                                                                                                                                       | DAY 467                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):                                                                           |                                                                                                     |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )                                                                                                            | <input type="checkbox"/>                                                                            |
| Chills                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Cough                                                                                                                                                                           | <input type="checkbox"/>                                                                            |
| Shortness of breath                                                                                                                                                             | <input type="checkbox"/>                                                                            |
| Difficulty breathing                                                                                                                                                            | <input type="checkbox"/>                                                                            |
| Fatigue                                                                                                                                                                         | <input type="checkbox"/>                                                                            |
| Muscle aches                                                                                                                                                                    | <input type="checkbox"/>                                                                            |
| Body aches                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Headache                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| New loss of taste                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| New loss of smell                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| Sore throat                                                                                                                                                                     | <input type="checkbox"/>                                                                            |
| Congestion                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Runny nose                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Nausea                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Vomiting                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Diarrhea                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?                                        | No <input type="radio"/><br>Yes <input type="radio"/>                                               |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

12 DEC 2021 23:59

US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:04

| TIMEPOINT                                                                                                                                                                       | DAY 474                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):                                                                           |                                                                                                     |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )                                                                                                            | <input type="checkbox"/>                                                                            |
| Chills                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Cough                                                                                                                                                                           | <input type="checkbox"/>                                                                            |
| Shortness of breath                                                                                                                                                             | <input type="checkbox"/>                                                                            |
| Difficulty breathing                                                                                                                                                            | <input type="checkbox"/>                                                                            |
| Fatigue                                                                                                                                                                         | <input type="checkbox"/>                                                                            |
| Muscle aches                                                                                                                                                                    | <input type="checkbox"/>                                                                            |
| Body aches                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Headache                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| New loss of taste                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| New loss of smell                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| Sore throat                                                                                                                                                                     | <input type="checkbox"/>                                                                            |
| Congestion                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Runny nose                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Nausea                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Vomiting                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Diarrhea                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?                                        | No <input type="radio"/><br>Yes <input type="radio"/>                                               |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

19 DEC 2021 23:59

US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:04

| TIMEPOINT                                                                                                                                                                       | DAY 481                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):                                                                           |                                                                                                     |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )                                                                                                            | <input type="checkbox"/>                                                                            |
| Chills                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Cough                                                                                                                                                                           | <input type="checkbox"/>                                                                            |
| Shortness of breath                                                                                                                                                             | <input type="checkbox"/>                                                                            |
| Difficulty breathing                                                                                                                                                            | <input type="checkbox"/>                                                                            |
| Fatigue                                                                                                                                                                         | <input type="checkbox"/>                                                                            |
| Muscle aches                                                                                                                                                                    | <input type="checkbox"/>                                                                            |
| Body aches                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Headache                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| New loss of taste                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| New loss of smell                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| Sore throat                                                                                                                                                                     | <input type="checkbox"/>                                                                            |
| Congestion                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Runny nose                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Nausea                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Vomiting                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Diarrhea                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?                                        | No <input type="radio"/><br>Yes <input type="radio"/>                                               |



**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

26 DEC 2021 23:59

US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:04

| TIMEPOINT                                                                                                                                                                       | DAY 488                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):                                                                           |                                                                                                     |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )                                                                                                            | <input type="checkbox"/>                                                                            |
| Chills                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Cough                                                                                                                                                                           | <input type="checkbox"/>                                                                            |
| Shortness of breath                                                                                                                                                             | <input type="checkbox"/>                                                                            |
| Difficulty breathing                                                                                                                                                            | <input type="checkbox"/>                                                                            |
| Fatigue                                                                                                                                                                         | <input type="checkbox"/>                                                                            |
| Muscle aches                                                                                                                                                                    | <input type="checkbox"/>                                                                            |
| Body aches                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Headache                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| New loss of taste                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| New loss of smell                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| Sore throat                                                                                                                                                                     | <input type="checkbox"/>                                                                            |
| Congestion                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Runny nose                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Nausea                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Vomiting                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Diarrhea                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?                                        | No <input type="radio"/><br>Yes <input type="radio"/>                                               |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

02 JAN 2022 23:59

US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:04

| TIMEPOINT                                                                                                                                                                       | DAY 495                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):                                                                           |                                                                                                     |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )                                                                                                            | <input type="checkbox"/>                                                                            |
| Chills                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Cough                                                                                                                                                                           | <input type="checkbox"/>                                                                            |
| Shortness of breath                                                                                                                                                             | <input type="checkbox"/>                                                                            |
| Difficulty breathing                                                                                                                                                            | <input type="checkbox"/>                                                                            |
| Fatigue                                                                                                                                                                         | <input type="checkbox"/>                                                                            |
| Muscle aches                                                                                                                                                                    | <input type="checkbox"/>                                                                            |
| Body aches                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Headache                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| New loss of taste                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| New loss of smell                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| Sore throat                                                                                                                                                                     | <input type="checkbox"/>                                                                            |
| Congestion                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Runny nose                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Nausea                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Vomiting                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Diarrhea                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?                                        | No <input type="radio"/><br>Yes <input type="radio"/>                                               |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

09 JAN 2022 23:59

US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:04

**TIMEPOINT**

DAY 502

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

16 JAN 2022 23:59

US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:04

**TIMEPOINT**

DAY 509

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐



**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

23 JAN 2022 23:59

US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:04

| TIMEPOINT                                                                                                                                                                       | DAY 516                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):                                                                           |                                                                                                     |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )                                                                                                            | <input type="checkbox"/>                                                                            |
| Chills                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Cough                                                                                                                                                                           | <input type="checkbox"/>                                                                            |
| Shortness of breath                                                                                                                                                             | <input type="checkbox"/>                                                                            |
| Difficulty breathing                                                                                                                                                            | <input type="checkbox"/>                                                                            |
| Fatigue                                                                                                                                                                         | <input type="checkbox"/>                                                                            |
| Muscle aches                                                                                                                                                                    | <input type="checkbox"/>                                                                            |
| Body aches                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Headache                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| New loss of taste                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| New loss of smell                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| Sore throat                                                                                                                                                                     | <input type="checkbox"/>                                                                            |
| Congestion                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Runny nose                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Nausea                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Vomiting                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Diarrhea                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?                                        | No <input type="radio"/><br>Yes <input type="radio"/>                                               |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

30 JAN 2022 23:59

US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:04

TIMEPOINT

DAY 523

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

06 FEB 2022 23:59

US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:04

| TIMEPOINT                                                                                                                                                                       | DAY 530                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):                                                                           |                                                                                                     |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )                                                                                                            | <input type="checkbox"/>                                                                            |
| Chills                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Cough                                                                                                                                                                           | <input type="checkbox"/>                                                                            |
| Shortness of breath                                                                                                                                                             | <input type="checkbox"/>                                                                            |
| Difficulty breathing                                                                                                                                                            | <input type="checkbox"/>                                                                            |
| Fatigue                                                                                                                                                                         | <input type="checkbox"/>                                                                            |
| Muscle aches                                                                                                                                                                    | <input type="checkbox"/>                                                                            |
| Body aches                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Headache                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| New loss of taste                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| New loss of smell                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| Sore throat                                                                                                                                                                     | <input type="checkbox"/>                                                                            |
| Congestion                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Runny nose                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Nausea                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Vomiting                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Diarrhea                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?                                        | No <input type="radio"/><br>Yes <input type="radio"/>                                               |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

13 FEB 2022 23:59

US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:04

TIMEPOINT

DAY 537

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐



**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

20 FEB 2022 23:59

US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:04

| TIMEPOINT                                                                                                                                                                       | DAY 544                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):                                                                           |                                                                                                     |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )                                                                                                            | <input type="checkbox"/>                                                                            |
| Chills                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Cough                                                                                                                                                                           | <input type="checkbox"/>                                                                            |
| Shortness of breath                                                                                                                                                             | <input type="checkbox"/>                                                                            |
| Difficulty breathing                                                                                                                                                            | <input type="checkbox"/>                                                                            |
| Fatigue                                                                                                                                                                         | <input type="checkbox"/>                                                                            |
| Muscle aches                                                                                                                                                                    | <input type="checkbox"/>                                                                            |
| Body aches                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Headache                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| New loss of taste                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| New loss of smell                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| Sore throat                                                                                                                                                                     | <input type="checkbox"/>                                                                            |
| Congestion                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Runny nose                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Nausea                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Vomiting                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Diarrhea                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?                                        | No <input type="radio"/><br>Yes <input type="radio"/>                                               |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

27 FEB 2022 23:59

US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:04

| TIMEPOINT                                                                                                                                                                       | DAY 551                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):                                                                           |                                                                                                     |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )                                                                                                            | <input type="checkbox"/>                                                                            |
| Chills                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Cough                                                                                                                                                                           | <input type="checkbox"/>                                                                            |
| Shortness of breath                                                                                                                                                             | <input type="checkbox"/>                                                                            |
| Difficulty breathing                                                                                                                                                            | <input type="checkbox"/>                                                                            |
| Fatigue                                                                                                                                                                         | <input type="checkbox"/>                                                                            |
| Muscle aches                                                                                                                                                                    | <input type="checkbox"/>                                                                            |
| Body aches                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Headache                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| New loss of taste                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| New loss of smell                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| Sore throat                                                                                                                                                                     | <input type="checkbox"/>                                                                            |
| Congestion                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Runny nose                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Nausea                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Vomiting                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Diarrhea                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?                                        | No <input type="radio"/><br>Yes <input type="radio"/>                                               |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

06 MAR 2022 23:59

US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:04

| TIMEPOINT                                                                                                                                                                       | DAY 558                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):                                                                           |                                                                                                     |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )                                                                                                            | <input type="checkbox"/>                                                                            |
| Chills                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Cough                                                                                                                                                                           | <input type="checkbox"/>                                                                            |
| Shortness of breath                                                                                                                                                             | <input type="checkbox"/>                                                                            |
| Difficulty breathing                                                                                                                                                            | <input type="checkbox"/>                                                                            |
| Fatigue                                                                                                                                                                         | <input type="checkbox"/>                                                                            |
| Muscle aches                                                                                                                                                                    | <input type="checkbox"/>                                                                            |
| Body aches                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Headache                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| New loss of taste                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| New loss of smell                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| Sore throat                                                                                                                                                                     | <input type="checkbox"/>                                                                            |
| Congestion                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Runny nose                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Nausea                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Vomiting                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Diarrhea                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?                                        | No <input type="radio"/><br>Yes <input type="radio"/>                                               |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

13 MAR 2022 23:59

US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:04

TIMEPOINT

DAY 565

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐



**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

20 MAR 2022 23:59

US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:04

TIMEPOINT

DAY 572

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

27 MAR 2022 23:59

US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:04

TIMEPOINT

DAY 579

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

03 APR 2022 23:59

US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:04

TIMEPOINT

DAY 586

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

10 APR 2022 23:59

US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:04

TIMEPOINT

DAY 593

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐



**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

17 APR 2022 23:59

US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:04

| TIMEPOINT                                                                                                                                                                       | DAY 600                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):                                                                           |                                                                                                     |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )                                                                                                            | <input type="checkbox"/>                                                                            |
| Chills                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Cough                                                                                                                                                                           | <input type="checkbox"/>                                                                            |
| Shortness of breath                                                                                                                                                             | <input type="checkbox"/>                                                                            |
| Difficulty breathing                                                                                                                                                            | <input type="checkbox"/>                                                                            |
| Fatigue                                                                                                                                                                         | <input type="checkbox"/>                                                                            |
| Muscle aches                                                                                                                                                                    | <input type="checkbox"/>                                                                            |
| Body aches                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Headache                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| New loss of taste                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| New loss of smell                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| Sore throat                                                                                                                                                                     | <input type="checkbox"/>                                                                            |
| Congestion                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Runny nose                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Nausea                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Vomiting                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Diarrhea                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?                                        | No <input type="radio"/><br>Yes <input type="radio"/>                                               |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

24 APR 2022 23:59

US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:04

TIMEPOINT

DAY 607

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

01 MAY 2022 23:59

US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:04

| TIMEPOINT                                                                                                                                                                       | DAY 614                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):                                                                           |                                                                                                     |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )                                                                                                            | <input type="checkbox"/>                                                                            |
| Chills                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Cough                                                                                                                                                                           | <input type="checkbox"/>                                                                            |
| Shortness of breath                                                                                                                                                             | <input type="checkbox"/>                                                                            |
| Difficulty breathing                                                                                                                                                            | <input type="checkbox"/>                                                                            |
| Fatigue                                                                                                                                                                         | <input type="checkbox"/>                                                                            |
| Muscle aches                                                                                                                                                                    | <input type="checkbox"/>                                                                            |
| Body aches                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Headache                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| New loss of taste                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| New loss of smell                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| Sore throat                                                                                                                                                                     | <input type="checkbox"/>                                                                            |
| Congestion                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Runny nose                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Nausea                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Vomiting                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Diarrhea                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?                                        | No <input type="radio"/><br>Yes <input type="radio"/>                                               |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

08 MAY 2022 23:59

US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:04

| TIMEPOINT                                                                                                                                                                       | DAY 621                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):                                                                           |                                                                                                     |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )                                                                                                            | <input type="checkbox"/>                                                                            |
| Chills                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Cough                                                                                                                                                                           | <input type="checkbox"/>                                                                            |
| Shortness of breath                                                                                                                                                             | <input type="checkbox"/>                                                                            |
| Difficulty breathing                                                                                                                                                            | <input type="checkbox"/>                                                                            |
| Fatigue                                                                                                                                                                         | <input type="checkbox"/>                                                                            |
| Muscle aches                                                                                                                                                                    | <input type="checkbox"/>                                                                            |
| Body aches                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Headache                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| New loss of taste                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| New loss of smell                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| Sore throat                                                                                                                                                                     | <input type="checkbox"/>                                                                            |
| Congestion                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Runny nose                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Nausea                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Vomiting                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Diarrhea                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?                                        | No <input type="radio"/><br>Yes <input type="radio"/>                                               |



**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

15 MAY 2022 23:59

US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:04

TIMEPOINT

DAY 628

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

22 MAY 2022 23:59

US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:04

TIMEPOINT

DAY 635

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

29 MAY 2022 23:59

US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:04

| TIMEPOINT                                                                                                                                                                       | DAY 642                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):                                                                           |                                                                                                     |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )                                                                                                            | <input type="checkbox"/>                                                                            |
| Chills                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Cough                                                                                                                                                                           | <input type="checkbox"/>                                                                            |
| Shortness of breath                                                                                                                                                             | <input type="checkbox"/>                                                                            |
| Difficulty breathing                                                                                                                                                            | <input type="checkbox"/>                                                                            |
| Fatigue                                                                                                                                                                         | <input type="checkbox"/>                                                                            |
| Muscle aches                                                                                                                                                                    | <input type="checkbox"/>                                                                            |
| Body aches                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Headache                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| New loss of taste                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| New loss of smell                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| Sore throat                                                                                                                                                                     | <input type="checkbox"/>                                                                            |
| Congestion                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Runny nose                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Nausea                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Vomiting                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Diarrhea                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?                                        | No <input type="radio"/><br>Yes <input type="radio"/>                                               |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

05 JUN 2022 23:59

US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:04

| TIMEPOINT                                                                                                                                                                       | DAY 649                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):                                                                           |                                                                                                     |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )                                                                                                            | <input type="checkbox"/>                                                                            |
| Chills                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Cough                                                                                                                                                                           | <input type="checkbox"/>                                                                            |
| Shortness of breath                                                                                                                                                             | <input type="checkbox"/>                                                                            |
| Difficulty breathing                                                                                                                                                            | <input type="checkbox"/>                                                                            |
| Fatigue                                                                                                                                                                         | <input type="checkbox"/>                                                                            |
| Muscle aches                                                                                                                                                                    | <input type="checkbox"/>                                                                            |
| Body aches                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Headache                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| New loss of taste                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| New loss of smell                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| Sore throat                                                                                                                                                                     | <input type="checkbox"/>                                                                            |
| Congestion                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Runny nose                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Nausea                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Vomiting                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Diarrhea                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?                                        | No <input type="radio"/><br>Yes <input type="radio"/>                                               |



**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

12 JUN 2022 23:59

US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:04

| TIMEPOINT                                                                                                                                                                       | DAY 656                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):                                                                           |                                                                                                     |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )                                                                                                            | <input type="checkbox"/>                                                                            |
| Chills                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Cough                                                                                                                                                                           | <input type="checkbox"/>                                                                            |
| Shortness of breath                                                                                                                                                             | <input type="checkbox"/>                                                                            |
| Difficulty breathing                                                                                                                                                            | <input type="checkbox"/>                                                                            |
| Fatigue                                                                                                                                                                         | <input type="checkbox"/>                                                                            |
| Muscle aches                                                                                                                                                                    | <input type="checkbox"/>                                                                            |
| Body aches                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Headache                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| New loss of taste                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| New loss of smell                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| Sore throat                                                                                                                                                                     | <input type="checkbox"/>                                                                            |
| Congestion                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Runny nose                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Nausea                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Vomiting                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Diarrhea                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?                                        | No <input type="radio"/><br>Yes <input type="radio"/>                                               |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

19 JUN 2022 23:59

US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:04

TIMEPOINT

DAY 663

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

26 JUN 2022 23:59

US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:04

**TIMEPOINT**

DAY 670

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

03 JUL 2022 23:59

US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:04

TIMEPOINT

DAY 677

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐



**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

10 JUL 2022 23:59

US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:04

| TIMEPOINT                                                                                                                                                                       | DAY 684                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):                                                                           |                                                                                                     |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )                                                                                                            | <input type="checkbox"/>                                                                            |
| Chills                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Cough                                                                                                                                                                           | <input type="checkbox"/>                                                                            |
| Shortness of breath                                                                                                                                                             | <input type="checkbox"/>                                                                            |
| Difficulty breathing                                                                                                                                                            | <input type="checkbox"/>                                                                            |
| Fatigue                                                                                                                                                                         | <input type="checkbox"/>                                                                            |
| Muscle aches                                                                                                                                                                    | <input type="checkbox"/>                                                                            |
| Body aches                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Headache                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| New loss of taste                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| New loss of smell                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| Sore throat                                                                                                                                                                     | <input type="checkbox"/>                                                                            |
| Congestion                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Runny nose                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Nausea                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Vomiting                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Diarrhea                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?                                        | No <input type="radio"/><br>Yes <input type="radio"/>                                               |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

17 JUL 2022 23:59

US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:04

| TIMEPOINT                                                                                                                                                                       | DAY 691                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):                                                                           |                                                                                                     |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )                                                                                                            | <input type="checkbox"/>                                                                            |
| Chills                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Cough                                                                                                                                                                           | <input type="checkbox"/>                                                                            |
| Shortness of breath                                                                                                                                                             | <input type="checkbox"/>                                                                            |
| Difficulty breathing                                                                                                                                                            | <input type="checkbox"/>                                                                            |
| Fatigue                                                                                                                                                                         | <input type="checkbox"/>                                                                            |
| Muscle aches                                                                                                                                                                    | <input type="checkbox"/>                                                                            |
| Body aches                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Headache                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| New loss of taste                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| New loss of smell                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| Sore throat                                                                                                                                                                     | <input type="checkbox"/>                                                                            |
| Congestion                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Runny nose                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Nausea                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Vomiting                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Diarrhea                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?                                        | No <input type="radio"/><br>Yes <input type="radio"/>                                               |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

24 JUL 2022 23:59

US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:04

| TIMEPOINT                                                                                                                                                                       | DAY 698                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):                                                                           |                                                                                                     |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )                                                                                                            | <input type="checkbox"/>                                                                            |
| Chills                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Cough                                                                                                                                                                           | <input type="checkbox"/>                                                                            |
| Shortness of breath                                                                                                                                                             | <input type="checkbox"/>                                                                            |
| Difficulty breathing                                                                                                                                                            | <input type="checkbox"/>                                                                            |
| Fatigue                                                                                                                                                                         | <input type="checkbox"/>                                                                            |
| Muscle aches                                                                                                                                                                    | <input type="checkbox"/>                                                                            |
| Body aches                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Headache                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| New loss of taste                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| New loss of smell                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| Sore throat                                                                                                                                                                     | <input type="checkbox"/>                                                                            |
| Congestion                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Runny nose                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Nausea                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Vomiting                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Diarrhea                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?                                        | No <input type="radio"/><br>Yes <input type="radio"/>                                               |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 JUL 2022 00:01

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31 JUL 2022 23:59

US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:04

TIMEPOINT

DAY 705

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐



**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

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Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

07 AUG 2022 23:59

US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:04

| TIMEPOINT                                                                                                                                                                       | DAY 712                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):                                                                           |                                                                                                     |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )                                                                                                            | <input type="checkbox"/>                                                                            |
| Chills                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Cough                                                                                                                                                                           | <input type="checkbox"/>                                                                            |
| Shortness of breath                                                                                                                                                             | <input type="checkbox"/>                                                                            |
| Difficulty breathing                                                                                                                                                            | <input type="checkbox"/>                                                                            |
| Fatigue                                                                                                                                                                         | <input type="checkbox"/>                                                                            |
| Muscle aches                                                                                                                                                                    | <input type="checkbox"/>                                                                            |
| Body aches                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Headache                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| New loss of taste                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| New loss of smell                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| Sore throat                                                                                                                                                                     | <input type="checkbox"/>                                                                            |
| Congestion                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Runny nose                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Nausea                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Vomiting                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Diarrhea                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?                                        | No <input type="radio"/><br>Yes <input type="radio"/>                                               |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

14 AUG 2022 23:59

US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:04

| TIMEPOINT                                                                                                                                                                       | DAY 719                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):                                                                           |                                                                                                     |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )                                                                                                            | <input type="checkbox"/>                                                                            |
| Chills                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Cough                                                                                                                                                                           | <input type="checkbox"/>                                                                            |
| Shortness of breath                                                                                                                                                             | <input type="checkbox"/>                                                                            |
| Difficulty breathing                                                                                                                                                            | <input type="checkbox"/>                                                                            |
| Fatigue                                                                                                                                                                         | <input type="checkbox"/>                                                                            |
| Muscle aches                                                                                                                                                                    | <input type="checkbox"/>                                                                            |
| Body aches                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Headache                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| New loss of taste                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| New loss of smell                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| Sore throat                                                                                                                                                                     | <input type="checkbox"/>                                                                            |
| Congestion                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Runny nose                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Nausea                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Vomiting                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Diarrhea                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?                                        | No <input type="radio"/><br>Yes <input type="radio"/>                                               |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 AUG 2022 00:01

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21 AUG 2022 23:59

US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:04

**TIMEPOINT**

DAY 726

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

28 AUG 2022 23:59

US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:04

| TIMEPOINT                                                                                                                                                                       | DAY 733                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):                                                                           |                                                                                                     |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )                                                                                                            | <input type="checkbox"/>                                                                            |
| Chills                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Cough                                                                                                                                                                           | <input type="checkbox"/>                                                                            |
| Shortness of breath                                                                                                                                                             | <input type="checkbox"/>                                                                            |
| Difficulty breathing                                                                                                                                                            | <input type="checkbox"/>                                                                            |
| Fatigue                                                                                                                                                                         | <input type="checkbox"/>                                                                            |
| Muscle aches                                                                                                                                                                    | <input type="checkbox"/>                                                                            |
| Body aches                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Headache                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| New loss of taste                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| New loss of smell                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| Sore throat                                                                                                                                                                     | <input type="checkbox"/>                                                                            |
| Congestion                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Runny nose                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Nausea                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Vomiting                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Diarrhea                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?                                        | No <input type="radio"/><br>Yes <input type="radio"/>                                               |



**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

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Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

04 SEP 2022 23:59

US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:04

| TIMEPOINT                                                                                                                                                                       | DAY 740                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):                                                                           |                                                                                                     |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )                                                                                                            | <input type="checkbox"/>                                                                            |
| Chills                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Cough                                                                                                                                                                           | <input type="checkbox"/>                                                                            |
| Shortness of breath                                                                                                                                                             | <input type="checkbox"/>                                                                            |
| Difficulty breathing                                                                                                                                                            | <input type="checkbox"/>                                                                            |
| Fatigue                                                                                                                                                                         | <input type="checkbox"/>                                                                            |
| Muscle aches                                                                                                                                                                    | <input type="checkbox"/>                                                                            |
| Body aches                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Headache                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| New loss of taste                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| New loss of smell                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| Sore throat                                                                                                                                                                     | <input type="checkbox"/>                                                                            |
| Congestion                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Runny nose                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Nausea                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Vomiting                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Diarrhea                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?                                        | No <input type="radio"/><br>Yes <input type="radio"/>                                               |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

11 SEP 2022 23:59

US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:04

| TIMEPOINT                                                                                                                                                                       | DAY 747                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):                                                                           |                                                                                                     |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )                                                                                                            | <input type="checkbox"/>                                                                            |
| Chills                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Cough                                                                                                                                                                           | <input type="checkbox"/>                                                                            |
| Shortness of breath                                                                                                                                                             | <input type="checkbox"/>                                                                            |
| Difficulty breathing                                                                                                                                                            | <input type="checkbox"/>                                                                            |
| Fatigue                                                                                                                                                                         | <input type="checkbox"/>                                                                            |
| Muscle aches                                                                                                                                                                    | <input type="checkbox"/>                                                                            |
| Body aches                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Headache                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| New loss of taste                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| New loss of smell                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| Sore throat                                                                                                                                                                     | <input type="checkbox"/>                                                                            |
| Congestion                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Runny nose                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Nausea                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Vomiting                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Diarrhea                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?                                        | No <input type="radio"/><br>Yes <input type="radio"/>                                               |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

18 SEP 2022 23:59

US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:04

| TIMEPOINT                                                                                                                                                                       | DAY 754                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):                                                                           |                                                                                                     |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )                                                                                                            | <input type="checkbox"/>                                                                            |
| Chills                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Cough                                                                                                                                                                           | <input type="checkbox"/>                                                                            |
| Shortness of breath                                                                                                                                                             | <input type="checkbox"/>                                                                            |
| Difficulty breathing                                                                                                                                                            | <input type="checkbox"/>                                                                            |
| Fatigue                                                                                                                                                                         | <input type="checkbox"/>                                                                            |
| Muscle aches                                                                                                                                                                    | <input type="checkbox"/>                                                                            |
| Body aches                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Headache                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| New loss of taste                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| New loss of smell                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| Sore throat                                                                                                                                                                     | <input type="checkbox"/>                                                                            |
| Congestion                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Runny nose                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Nausea                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Vomiting                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Diarrhea                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?                                        | No <input type="radio"/><br>Yes <input type="radio"/>                                               |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

25 SEP 2022 23:59

US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:04

| TIMEPOINT                                                                                                                                                                       | DAY 761                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):                                                                           |                                                                                                     |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )                                                                                                            | <input type="checkbox"/>                                                                            |
| Chills                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Cough                                                                                                                                                                           | <input type="checkbox"/>                                                                            |
| Shortness of breath                                                                                                                                                             | <input type="checkbox"/>                                                                            |
| Difficulty breathing                                                                                                                                                            | <input type="checkbox"/>                                                                            |
| Fatigue                                                                                                                                                                         | <input type="checkbox"/>                                                                            |
| Muscle aches                                                                                                                                                                    | <input type="checkbox"/>                                                                            |
| Body aches                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Headache                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| New loss of taste                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| New loss of smell                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| Sore throat                                                                                                                                                                     | <input type="checkbox"/>                                                                            |
| Congestion                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Runny nose                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Nausea                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Vomiting                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Diarrhea                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?                                        | No <input type="radio"/><br>Yes <input type="radio"/>                                               |



**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

02 OCT 2022 23:59

US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:04

| TIMEPOINT                                                                                                                                                                       | DAY 768                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):                                                                           |                                                                                                     |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )                                                                                                            | <input type="checkbox"/>                                                                            |
| Chills                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Cough                                                                                                                                                                           | <input type="checkbox"/>                                                                            |
| Shortness of breath                                                                                                                                                             | <input type="checkbox"/>                                                                            |
| Difficulty breathing                                                                                                                                                            | <input type="checkbox"/>                                                                            |
| Fatigue                                                                                                                                                                         | <input type="checkbox"/>                                                                            |
| Muscle aches                                                                                                                                                                    | <input type="checkbox"/>                                                                            |
| Body aches                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Headache                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| New loss of taste                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| New loss of smell                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| Sore throat                                                                                                                                                                     | <input type="checkbox"/>                                                                            |
| Congestion                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Runny nose                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Nausea                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Vomiting                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Diarrhea                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?                                        | No <input type="radio"/><br>Yes <input type="radio"/>                                               |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

09 OCT 2022 23:59

US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:04

| TIMEPOINT                                                                                                                                                                       | DAY 775                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):                                                                           |                                                                                                     |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )                                                                                                            | <input type="checkbox"/>                                                                            |
| Chills                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Cough                                                                                                                                                                           | <input type="checkbox"/>                                                                            |
| Shortness of breath                                                                                                                                                             | <input type="checkbox"/>                                                                            |
| Difficulty breathing                                                                                                                                                            | <input type="checkbox"/>                                                                            |
| Fatigue                                                                                                                                                                         | <input type="checkbox"/>                                                                            |
| Muscle aches                                                                                                                                                                    | <input type="checkbox"/>                                                                            |
| Body aches                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Headache                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| New loss of taste                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| New loss of smell                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| Sore throat                                                                                                                                                                     | <input type="checkbox"/>                                                                            |
| Congestion                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Runny nose                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Nausea                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Vomiting                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Diarrhea                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?                                        | No <input type="radio"/><br>Yes <input type="radio"/>                                               |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

16 OCT 2022 23:59

US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:04

TIMEPOINT

DAY 782

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

23 OCT 2022 23:59

US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:04

| TIMEPOINT                                                                                                                                                                       | DAY 789                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):                                                                           |                                                                                                     |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )                                                                                                            | <input type="checkbox"/>                                                                            |
| Chills                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Cough                                                                                                                                                                           | <input type="checkbox"/>                                                                            |
| Shortness of breath                                                                                                                                                             | <input type="checkbox"/>                                                                            |
| Difficulty breathing                                                                                                                                                            | <input type="checkbox"/>                                                                            |
| Fatigue                                                                                                                                                                         | <input type="checkbox"/>                                                                            |
| Muscle aches                                                                                                                                                                    | <input type="checkbox"/>                                                                            |
| Body aches                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Headache                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| New loss of taste                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| New loss of smell                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| Sore throat                                                                                                                                                                     | <input type="checkbox"/>                                                                            |
| Congestion                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Runny nose                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Nausea                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Vomiting                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Diarrhea                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?                                        | No <input type="radio"/><br>Yes <input type="radio"/>                                               |



**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

30 OCT 2022 23:59

US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:04

TIMEPOINT

DAY 796

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

06 NOV 2022 23:59

**US3742169**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 11:15:04**

Was Contact Attempted? Yes ☐  
No ☐

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3742169

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:15:04

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 11:15:04

|                                                  |                                                                  |
|--------------------------------------------------|------------------------------------------------------------------|
| Date of Contact                                  | 06 NOV 2020                                                      |
| Time of Contact                                  | 12:20                                                            |
| Date and Time of Contact (derived)               | 06 NOV 2020 12:20                                                |
| Type of Contact                                  | Clinic Visit - Scheduled <input type="checkbox"/>                |
|                                                  | Clinical Visit - Unscheduled <input checked="" type="checkbox"/> |
|                                                  | Safety Call <input type="checkbox"/>                             |
|                                                  | Convalescent Tele-visit <input type="checkbox"/>                 |
| Has the subject reported symptoms of SARS-COV-2? | Yes <input checked="" type="checkbox"/>                          |
|                                                  | No <input type="checkbox"/>                                      |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:15:04

Symptom Day

|        |                                     |
|--------|-------------------------------------|
| Day 1  | <input checked="" type="checkbox"/> |
| Day 2  | <input type="checkbox"/>            |
| Day 3  | <input type="checkbox"/>            |
| Day 4  | <input type="checkbox"/>            |
| Day 5  | <input type="checkbox"/>            |
| Day 6  | <input type="checkbox"/>            |
| Day 7  | <input type="checkbox"/>            |
| Day 8  | <input type="checkbox"/>            |
| Day 9  | <input type="checkbox"/>            |
| Day 10 | <input type="checkbox"/>            |
| Day 11 | <input type="checkbox"/>            |
| Day 12 | <input type="checkbox"/>            |
| Day 13 | <input type="checkbox"/>            |
| Day 14 | <input type="checkbox"/>            |
| Day 15 | <input type="checkbox"/>            |
| Day 16 | <input type="checkbox"/>            |
| Day 17 | <input type="checkbox"/>            |
| Day 18 | <input type="checkbox"/>            |
| Day 19 | <input type="checkbox"/>            |
| Day 20 | <input type="checkbox"/>            |
| Day 21 | <input type="checkbox"/>            |
| Day 22 | <input type="checkbox"/>            |
| Day 23 | <input type="checkbox"/>            |
| Day 24 | <input type="checkbox"/>            |
| Day 25 | <input type="checkbox"/>            |
| Day 26 | <input type="checkbox"/>            |
| Day 27 | <input type="checkbox"/>            |
| Day 28 | <input type="checkbox"/>            |
| Day 29 | <input type="checkbox"/>            |
| Day 30 | <input type="checkbox"/>            |
| Day 31 | <input type="checkbox"/>            |
| Day 32 | <input type="checkbox"/>            |
| Day 33 | <input type="checkbox"/>            |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:15:04

|                      |             |                                     |
|----------------------|-------------|-------------------------------------|
|                      | Day 34      | <input type="checkbox"/>            |
|                      | Day 35      | <input type="checkbox"/>            |
|                      | Day 36      | <input type="checkbox"/>            |
|                      | Day 37      | <input type="checkbox"/>            |
|                      | Day 38      | <input type="checkbox"/>            |
|                      | Day 39      | <input type="checkbox"/>            |
|                      | Day 40      | <input type="checkbox"/>            |
| Date                 | 30 OCT 2020 |                                     |
| Assessment Not Done  | False       |                                     |
| O2 Saturation        |             |                                     |
| O2 Saturation Units  |             |                                     |
| Temperature          |             |                                     |
| Chills               | None        | <input type="checkbox"/>            |
|                      | Mild        | <input checked="" type="checkbox"/> |
|                      | Moderate    | <input type="checkbox"/>            |
|                      | Severe      | <input type="checkbox"/>            |
|                      | Not Done    | <input type="checkbox"/>            |
| Cough                | None        | <input checked="" type="checkbox"/> |
|                      | Mild        | <input type="checkbox"/>            |
|                      | Moderate    | <input type="checkbox"/>            |
|                      | Severe      | <input type="checkbox"/>            |
|                      | Not Done    | <input type="checkbox"/>            |
| Shortness of Breath  | None        | <input checked="" type="checkbox"/> |
|                      | Mild        | <input type="checkbox"/>            |
|                      | Moderate    | <input type="checkbox"/>            |
|                      | Severe      | <input type="checkbox"/>            |
|                      | Not Done    | <input type="checkbox"/>            |
| Difficulty Breathing | None        | <input checked="" type="checkbox"/> |
|                      | Mild        | <input type="checkbox"/>            |
|                      | Moderate    | <input type="checkbox"/>            |
|                      | Severe      | <input type="checkbox"/>            |
|                      | Not Done    | <input type="checkbox"/>            |
| Fatigue              | None        | <input checked="" type="checkbox"/> |
| v6.020 DTW (1102)    | 311 of 2382 |                                     |



US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:15:04

|                        |          |                                     |
|------------------------|----------|-------------------------------------|
|                        | Mild     | <input type="checkbox"/>            |
|                        | Moderate | <input type="checkbox"/>            |
|                        | Severe   | <input type="checkbox"/>            |
|                        | Not Done | <input type="checkbox"/>            |
| Muscle Aches (Myalgia) | None     | <input checked="" type="checkbox"/> |
|                        | Mild     | <input type="checkbox"/>            |
|                        | Moderate | <input type="checkbox"/>            |
|                        | Severe   | <input type="checkbox"/>            |
|                        | Not Done | <input type="checkbox"/>            |
| Body Aches             | None     | <input checked="" type="checkbox"/> |
|                        | Mild     | <input type="checkbox"/>            |
|                        | Moderate | <input type="checkbox"/>            |
|                        | Severe   | <input type="checkbox"/>            |
|                        | Not Done | <input type="checkbox"/>            |
| Headache               | None     | <input checked="" type="checkbox"/> |
|                        | Mild     | <input type="checkbox"/>            |
|                        | Moderate | <input type="checkbox"/>            |
|                        | Severe   | <input type="checkbox"/>            |
|                        | Not Done | <input type="checkbox"/>            |
| New Loss of Taste      | None     | <input checked="" type="checkbox"/> |
|                        | Mild     | <input type="checkbox"/>            |
|                        | Moderate | <input type="checkbox"/>            |
|                        | Severe   | <input type="checkbox"/>            |
|                        | Not Done | <input type="checkbox"/>            |
| New Loss of Smell      | None     | <input checked="" type="checkbox"/> |
|                        | Mild     | <input type="checkbox"/>            |
|                        | Moderate | <input type="checkbox"/>            |
|                        | Severe   | <input type="checkbox"/>            |
|                        | Not Done | <input type="checkbox"/>            |
| Nasal Congestion       | None     | <input checked="" type="checkbox"/> |
|                        | Mild     | <input type="checkbox"/>            |
|                        | Moderate | <input type="checkbox"/>            |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:15:04

|                         |          |                                     |
|-------------------------|----------|-------------------------------------|
|                         | Severe   | <input type="checkbox"/>            |
|                         | Not Done | <input type="checkbox"/>            |
| Runny Nose (Rhinorrhea) | None     | <input checked="" type="checkbox"/> |
|                         | Mild     | <input type="checkbox"/>            |
|                         | Moderate | <input type="checkbox"/>            |
|                         | Severe   | <input type="checkbox"/>            |
|                         | Not Done | <input type="checkbox"/>            |
| Nausea                  | None     | <input checked="" type="checkbox"/> |
|                         | Mild     | <input type="checkbox"/>            |
|                         | Moderate | <input type="checkbox"/>            |
|                         | Severe   | <input type="checkbox"/>            |
|                         | Not Done | <input type="checkbox"/>            |
| Vomiting                | None     | <input checked="" type="checkbox"/> |
|                         | Mild     | <input type="checkbox"/>            |
|                         | Moderate | <input type="checkbox"/>            |
|                         | Severe   | <input type="checkbox"/>            |
|                         | Not Done | <input type="checkbox"/>            |
| Diarrhea                | None     | <input checked="" type="checkbox"/> |
|                         | Mild     | <input type="checkbox"/>            |
|                         | Moderate | <input type="checkbox"/>            |
|                         | Severe   | <input type="checkbox"/>            |
|                         | Not Done | <input type="checkbox"/>            |
| Sore Throat             | None     | <input checked="" type="checkbox"/> |
|                         | Mild     | <input type="checkbox"/>            |
|                         | Moderate | <input type="checkbox"/>            |
|                         | Severe   | <input type="checkbox"/>            |
|                         | Not Done | <input type="checkbox"/>            |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:15:04

Symptom Day

|        |                                     |
|--------|-------------------------------------|
| Day 1  | <input type="checkbox"/>            |
| Day 2  | <input checked="" type="checkbox"/> |
| Day 3  | <input type="checkbox"/>            |
| Day 4  | <input type="checkbox"/>            |
| Day 5  | <input type="checkbox"/>            |
| Day 6  | <input type="checkbox"/>            |
| Day 7  | <input type="checkbox"/>            |
| Day 8  | <input type="checkbox"/>            |
| Day 9  | <input type="checkbox"/>            |
| Day 10 | <input type="checkbox"/>            |
| Day 11 | <input type="checkbox"/>            |
| Day 12 | <input type="checkbox"/>            |
| Day 13 | <input type="checkbox"/>            |
| Day 14 | <input type="checkbox"/>            |
| Day 15 | <input type="checkbox"/>            |
| Day 16 | <input type="checkbox"/>            |
| Day 17 | <input type="checkbox"/>            |
| Day 18 | <input type="checkbox"/>            |
| Day 19 | <input type="checkbox"/>            |
| Day 20 | <input type="checkbox"/>            |
| Day 21 | <input type="checkbox"/>            |
| Day 22 | <input type="checkbox"/>            |
| Day 23 | <input type="checkbox"/>            |
| Day 24 | <input type="checkbox"/>            |
| Day 25 | <input type="checkbox"/>            |
| Day 26 | <input type="checkbox"/>            |
| Day 27 | <input type="checkbox"/>            |
| Day 28 | <input type="checkbox"/>            |
| Day 29 | <input type="checkbox"/>            |
| Day 30 | <input type="checkbox"/>            |
| Day 31 | <input type="checkbox"/>            |
| Day 32 | <input type="checkbox"/>            |
| Day 33 | <input type="checkbox"/>            |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:15:04

|                      |             |                                     |
|----------------------|-------------|-------------------------------------|
|                      | Day 34      | <input type="checkbox"/>            |
|                      | Day 35      | <input type="checkbox"/>            |
|                      | Day 36      | <input type="checkbox"/>            |
|                      | Day 37      | <input type="checkbox"/>            |
|                      | Day 38      | <input type="checkbox"/>            |
|                      | Day 39      | <input type="checkbox"/>            |
|                      | Day 40      | <input type="checkbox"/>            |
| Date                 | 31 OCT 2020 |                                     |
| Assessment Not Done  | False       |                                     |
| O2 Saturation        |             |                                     |
| O2 Saturation Units  |             |                                     |
| Temperature          |             |                                     |
| Chills               | None        | <input type="checkbox"/>            |
|                      | Mild        | <input checked="" type="checkbox"/> |
|                      | Moderate    | <input type="checkbox"/>            |
|                      | Severe      | <input type="checkbox"/>            |
|                      | Not Done    | <input type="checkbox"/>            |
| Cough                | None        | <input checked="" type="checkbox"/> |
|                      | Mild        | <input type="checkbox"/>            |
|                      | Moderate    | <input type="checkbox"/>            |
|                      | Severe      | <input type="checkbox"/>            |
|                      | Not Done    | <input type="checkbox"/>            |
| Shortness of Breath  | None        | <input checked="" type="checkbox"/> |
|                      | Mild        | <input type="checkbox"/>            |
|                      | Moderate    | <input type="checkbox"/>            |
|                      | Severe      | <input type="checkbox"/>            |
|                      | Not Done    | <input type="checkbox"/>            |
| Difficulty Breathing | None        | <input checked="" type="checkbox"/> |
|                      | Mild        | <input type="checkbox"/>            |
|                      | Moderate    | <input type="checkbox"/>            |
|                      | Severe      | <input type="checkbox"/>            |
|                      | Not Done    | <input type="checkbox"/>            |
| Fatigue              | None        | <input checked="" type="checkbox"/> |
| v6.020 DTW (1102)    | 315 of 2382 |                                     |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:15:04

|                        |          |                                     |
|------------------------|----------|-------------------------------------|
|                        | Mild     | <input type="checkbox"/>            |
|                        | Moderate | <input type="checkbox"/>            |
|                        | Severe   | <input type="checkbox"/>            |
|                        | Not Done | <input type="checkbox"/>            |
| Muscle Aches (Myalgia) | None     | <input type="checkbox"/>            |
|                        | Mild     | <input checked="" type="checkbox"/> |
|                        | Moderate | <input type="checkbox"/>            |
|                        | Severe   | <input type="checkbox"/>            |
|                        | Not Done | <input type="checkbox"/>            |
| Body Aches             | None     | <input checked="" type="checkbox"/> |
|                        | Mild     | <input type="checkbox"/>            |
|                        | Moderate | <input type="checkbox"/>            |
|                        | Severe   | <input type="checkbox"/>            |
|                        | Not Done | <input type="checkbox"/>            |
| Headache               | None     | <input type="checkbox"/>            |
|                        | Mild     | <input checked="" type="checkbox"/> |
|                        | Moderate | <input type="checkbox"/>            |
|                        | Severe   | <input type="checkbox"/>            |
|                        | Not Done | <input type="checkbox"/>            |
| New Loss of Taste      | None     | <input checked="" type="checkbox"/> |
|                        | Mild     | <input type="checkbox"/>            |
|                        | Moderate | <input type="checkbox"/>            |
|                        | Severe   | <input type="checkbox"/>            |
|                        | Not Done | <input type="checkbox"/>            |
| New Loss of Smell      | None     | <input checked="" type="checkbox"/> |
|                        | Mild     | <input type="checkbox"/>            |
|                        | Moderate | <input type="checkbox"/>            |
|                        | Severe   | <input type="checkbox"/>            |
|                        | Not Done | <input type="checkbox"/>            |
| Nasal Congestion       | None     | <input checked="" type="checkbox"/> |
|                        | Mild     | <input type="checkbox"/>            |
|                        | Moderate | <input type="checkbox"/>            |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:15:04

|                         |          |                                     |
|-------------------------|----------|-------------------------------------|
|                         | Severe   | <input type="checkbox"/>            |
|                         | Not Done | <input type="checkbox"/>            |
| Runny Nose (Rhinorrhea) | None     | <input checked="" type="checkbox"/> |
|                         | Mild     | <input type="checkbox"/>            |
|                         | Moderate | <input type="checkbox"/>            |
|                         | Severe   | <input type="checkbox"/>            |
|                         | Not Done | <input type="checkbox"/>            |
| Nausea                  | None     | <input checked="" type="checkbox"/> |
|                         | Mild     | <input type="checkbox"/>            |
|                         | Moderate | <input type="checkbox"/>            |
|                         | Severe   | <input type="checkbox"/>            |
|                         | Not Done | <input type="checkbox"/>            |
| Vomiting                | None     | <input checked="" type="checkbox"/> |
|                         | Mild     | <input type="checkbox"/>            |
|                         | Moderate | <input type="checkbox"/>            |
|                         | Severe   | <input type="checkbox"/>            |
|                         | Not Done | <input type="checkbox"/>            |
| Diarrhea                | None     | <input checked="" type="checkbox"/> |
|                         | Mild     | <input type="checkbox"/>            |
|                         | Moderate | <input type="checkbox"/>            |
|                         | Severe   | <input type="checkbox"/>            |
|                         | Not Done | <input type="checkbox"/>            |
| Sore Throat             | None     | <input checked="" type="checkbox"/> |
|                         | Mild     | <input type="checkbox"/>            |
|                         | Moderate | <input type="checkbox"/>            |
|                         | Severe   | <input type="checkbox"/>            |
|                         | Not Done | <input type="checkbox"/>            |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:15:04

Symptom Day

|        |                                     |
|--------|-------------------------------------|
| Day 1  | <input type="checkbox"/>            |
| Day 2  | <input type="checkbox"/>            |
| Day 3  | <input checked="" type="checkbox"/> |
| Day 4  | <input type="checkbox"/>            |
| Day 5  | <input type="checkbox"/>            |
| Day 6  | <input type="checkbox"/>            |
| Day 7  | <input type="checkbox"/>            |
| Day 8  | <input type="checkbox"/>            |
| Day 9  | <input type="checkbox"/>            |
| Day 10 | <input type="checkbox"/>            |
| Day 11 | <input type="checkbox"/>            |
| Day 12 | <input type="checkbox"/>            |
| Day 13 | <input type="checkbox"/>            |
| Day 14 | <input type="checkbox"/>            |
| Day 15 | <input type="checkbox"/>            |
| Day 16 | <input type="checkbox"/>            |
| Day 17 | <input type="checkbox"/>            |
| Day 18 | <input type="checkbox"/>            |
| Day 19 | <input type="checkbox"/>            |
| Day 20 | <input type="checkbox"/>            |
| Day 21 | <input type="checkbox"/>            |
| Day 22 | <input type="checkbox"/>            |
| Day 23 | <input type="checkbox"/>            |
| Day 24 | <input type="checkbox"/>            |
| Day 25 | <input type="checkbox"/>            |
| Day 26 | <input type="checkbox"/>            |
| Day 27 | <input type="checkbox"/>            |
| Day 28 | <input type="checkbox"/>            |
| Day 29 | <input type="checkbox"/>            |
| Day 30 | <input type="checkbox"/>            |
| Day 31 | <input type="checkbox"/>            |
| Day 32 | <input type="checkbox"/>            |
| Day 33 | <input type="checkbox"/>            |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:15:04

|                      |             |                                     |
|----------------------|-------------|-------------------------------------|
|                      | Day 34      | <input type="checkbox"/>            |
|                      | Day 35      | <input type="checkbox"/>            |
|                      | Day 36      | <input type="checkbox"/>            |
|                      | Day 37      | <input type="checkbox"/>            |
|                      | Day 38      | <input type="checkbox"/>            |
|                      | Day 39      | <input type="checkbox"/>            |
|                      | Day 40      | <input type="checkbox"/>            |
| Date                 | 01 NOV 2020 |                                     |
| Assessment Not Done  | False       |                                     |
| O2 Saturation        |             |                                     |
| O2 Saturation Units  |             |                                     |
| Temperature          |             |                                     |
| Chills               | None        | <input type="checkbox"/>            |
|                      | Mild        | <input checked="" type="checkbox"/> |
|                      | Moderate    | <input type="checkbox"/>            |
|                      | Severe      | <input type="checkbox"/>            |
|                      | Not Done    | <input type="checkbox"/>            |
| Cough                | None        | <input checked="" type="checkbox"/> |
|                      | Mild        | <input type="checkbox"/>            |
|                      | Moderate    | <input type="checkbox"/>            |
|                      | Severe      | <input type="checkbox"/>            |
|                      | Not Done    | <input type="checkbox"/>            |
| Shortness of Breath  | None        | <input checked="" type="checkbox"/> |
|                      | Mild        | <input type="checkbox"/>            |
|                      | Moderate    | <input type="checkbox"/>            |
|                      | Severe      | <input type="checkbox"/>            |
|                      | Not Done    | <input type="checkbox"/>            |
| Difficulty Breathing | None        | <input checked="" type="checkbox"/> |
|                      | Mild        | <input type="checkbox"/>            |
|                      | Moderate    | <input type="checkbox"/>            |
|                      | Severe      | <input type="checkbox"/>            |
|                      | Not Done    | <input type="checkbox"/>            |
| Fatigue              | None        | <input checked="" type="checkbox"/> |
| v6.020 DTW (1102)    | 319 of 2382 |                                     |



US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:15:04

|                        |          |                                  |
|------------------------|----------|----------------------------------|
|                        | Mild     | <input type="radio"/>            |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |
| Muscle Aches (Myalgia) | None     | <input checked="" type="radio"/> |
|                        | Mild     | <input type="radio"/>            |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |
| Body Aches             | None     | <input checked="" type="radio"/> |
|                        | Mild     | <input type="radio"/>            |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |
| Headache               | None     | <input type="radio"/>            |
|                        | Mild     | <input checked="" type="radio"/> |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |
| New Loss of Taste      | None     | <input checked="" type="radio"/> |
|                        | Mild     | <input type="radio"/>            |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |
| New Loss of Smell      | None     | <input checked="" type="radio"/> |
|                        | Mild     | <input type="radio"/>            |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |
| Nasal Congestion       | None     | <input checked="" type="radio"/> |
|                        | Mild     | <input type="radio"/>            |
|                        | Moderate | <input type="radio"/>            |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:15:04

|                         |          |                                     |
|-------------------------|----------|-------------------------------------|
|                         | Severe   | <input type="checkbox"/>            |
|                         | Not Done | <input type="checkbox"/>            |
| Runny Nose (Rhinorrhea) | None     | <input checked="" type="checkbox"/> |
|                         | Mild     | <input type="checkbox"/>            |
|                         | Moderate | <input type="checkbox"/>            |
|                         | Severe   | <input type="checkbox"/>            |
|                         | Not Done | <input type="checkbox"/>            |
| Nausea                  | None     | <input checked="" type="checkbox"/> |
|                         | Mild     | <input type="checkbox"/>            |
|                         | Moderate | <input type="checkbox"/>            |
|                         | Severe   | <input type="checkbox"/>            |
|                         | Not Done | <input type="checkbox"/>            |
| Vomiting                | None     | <input checked="" type="checkbox"/> |
|                         | Mild     | <input type="checkbox"/>            |
|                         | Moderate | <input type="checkbox"/>            |
|                         | Severe   | <input type="checkbox"/>            |
|                         | Not Done | <input type="checkbox"/>            |
| Diarrhea                | None     | <input checked="" type="checkbox"/> |
|                         | Mild     | <input type="checkbox"/>            |
|                         | Moderate | <input type="checkbox"/>            |
|                         | Severe   | <input type="checkbox"/>            |
|                         | Not Done | <input type="checkbox"/>            |
| Sore Throat             | None     | <input checked="" type="checkbox"/> |
|                         | Mild     | <input type="checkbox"/>            |
|                         | Moderate | <input type="checkbox"/>            |
|                         | Severe   | <input type="checkbox"/>            |
|                         | Not Done | <input type="checkbox"/>            |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:15:04

[Symptom Day](#)

|        |                                     |
|--------|-------------------------------------|
| Day 1  | <input type="checkbox"/>            |
| Day 2  | <input type="checkbox"/>            |
| Day 3  | <input type="checkbox"/>            |
| Day 4  | <input checked="" type="checkbox"/> |
| Day 5  | <input type="checkbox"/>            |
| Day 6  | <input type="checkbox"/>            |
| Day 7  | <input type="checkbox"/>            |
| Day 8  | <input type="checkbox"/>            |
| Day 9  | <input type="checkbox"/>            |
| Day 10 | <input type="checkbox"/>            |
| Day 11 | <input type="checkbox"/>            |
| Day 12 | <input type="checkbox"/>            |
| Day 13 | <input type="checkbox"/>            |
| Day 14 | <input type="checkbox"/>            |
| Day 15 | <input type="checkbox"/>            |
| Day 16 | <input type="checkbox"/>            |
| Day 17 | <input type="checkbox"/>            |
| Day 18 | <input type="checkbox"/>            |
| Day 19 | <input type="checkbox"/>            |
| Day 20 | <input type="checkbox"/>            |
| Day 21 | <input type="checkbox"/>            |
| Day 22 | <input type="checkbox"/>            |
| Day 23 | <input type="checkbox"/>            |
| Day 24 | <input type="checkbox"/>            |
| Day 25 | <input type="checkbox"/>            |
| Day 26 | <input type="checkbox"/>            |
| Day 27 | <input type="checkbox"/>            |
| Day 28 | <input type="checkbox"/>            |
| Day 29 | <input type="checkbox"/>            |
| Day 30 | <input type="checkbox"/>            |
| Day 31 | <input type="checkbox"/>            |
| Day 32 | <input type="checkbox"/>            |
| Day 33 | <input type="checkbox"/>            |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:15:04

|                      |             |                                     |
|----------------------|-------------|-------------------------------------|
|                      | Day 34      | <input type="checkbox"/>            |
|                      | Day 35      | <input type="checkbox"/>            |
|                      | Day 36      | <input type="checkbox"/>            |
|                      | Day 37      | <input type="checkbox"/>            |
|                      | Day 38      | <input type="checkbox"/>            |
|                      | Day 39      | <input type="checkbox"/>            |
|                      | Day 40      | <input type="checkbox"/>            |
| Date                 | 02 NOV 2020 |                                     |
| Assessment Not Done  | False       |                                     |
| O2 Saturation        |             |                                     |
| O2 Saturation Units  |             |                                     |
| Temperature          |             |                                     |
| Chills               | None        | <input type="checkbox"/>            |
|                      | Mild        | <input checked="" type="checkbox"/> |
|                      | Moderate    | <input type="checkbox"/>            |
|                      | Severe      | <input type="checkbox"/>            |
|                      | Not Done    | <input type="checkbox"/>            |
| Cough                | None        | <input checked="" type="checkbox"/> |
|                      | Mild        | <input type="checkbox"/>            |
|                      | Moderate    | <input type="checkbox"/>            |
|                      | Severe      | <input type="checkbox"/>            |
|                      | Not Done    | <input type="checkbox"/>            |
| Shortness of Breath  | None        | <input checked="" type="checkbox"/> |
|                      | Mild        | <input type="checkbox"/>            |
|                      | Moderate    | <input type="checkbox"/>            |
|                      | Severe      | <input type="checkbox"/>            |
|                      | Not Done    | <input type="checkbox"/>            |
| Difficulty Breathing | None        | <input checked="" type="checkbox"/> |
|                      | Mild        | <input type="checkbox"/>            |
|                      | Moderate    | <input type="checkbox"/>            |
|                      | Severe      | <input type="checkbox"/>            |
|                      | Not Done    | <input type="checkbox"/>            |
| Fatigue              | None        | <input checked="" type="checkbox"/> |
| v6.020 DTW (1102)    | 323 of 2382 |                                     |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:15:04

|                        |          |                                  |
|------------------------|----------|----------------------------------|
|                        | Mild     | <input type="radio"/>            |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |
| Muscle Aches (Myalgia) | None     | <input checked="" type="radio"/> |
|                        | Mild     | <input type="radio"/>            |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |
| Body Aches             | None     | <input checked="" type="radio"/> |
|                        | Mild     | <input type="radio"/>            |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |
| Headache               | None     | <input type="radio"/>            |
|                        | Mild     | <input checked="" type="radio"/> |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |
| New Loss of Taste      | None     | <input checked="" type="radio"/> |
|                        | Mild     | <input type="radio"/>            |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |
| New Loss of Smell      | None     | <input checked="" type="radio"/> |
|                        | Mild     | <input type="radio"/>            |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |
| Nasal Congestion       | None     | <input checked="" type="radio"/> |
|                        | Mild     | <input type="radio"/>            |
|                        | Moderate | <input type="radio"/>            |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:15:04

|                         |          |                                     |
|-------------------------|----------|-------------------------------------|
|                         | Severe   | <input type="checkbox"/>            |
|                         | Not Done | <input type="checkbox"/>            |
| Runny Nose (Rhinorrhea) | None     | <input checked="" type="checkbox"/> |
|                         | Mild     | <input type="checkbox"/>            |
|                         | Moderate | <input type="checkbox"/>            |
|                         | Severe   | <input type="checkbox"/>            |
|                         | Not Done | <input type="checkbox"/>            |
| Nausea                  | None     | <input checked="" type="checkbox"/> |
|                         | Mild     | <input type="checkbox"/>            |
|                         | Moderate | <input type="checkbox"/>            |
|                         | Severe   | <input type="checkbox"/>            |
|                         | Not Done | <input type="checkbox"/>            |
| Vomiting                | None     | <input checked="" type="checkbox"/> |
|                         | Mild     | <input type="checkbox"/>            |
|                         | Moderate | <input type="checkbox"/>            |
|                         | Severe   | <input type="checkbox"/>            |
|                         | Not Done | <input type="checkbox"/>            |
| Diarrhea                | None     | <input checked="" type="checkbox"/> |
|                         | Mild     | <input type="checkbox"/>            |
|                         | Moderate | <input type="checkbox"/>            |
|                         | Severe   | <input type="checkbox"/>            |
|                         | Not Done | <input type="checkbox"/>            |
| Sore Throat             | None     | <input checked="" type="checkbox"/> |
|                         | Mild     | <input type="checkbox"/>            |
|                         | Moderate | <input type="checkbox"/>            |
|                         | Severe   | <input type="checkbox"/>            |
|                         | Not Done | <input type="checkbox"/>            |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:15:04

[Symptom Day](#)

|        |                                     |
|--------|-------------------------------------|
| Day 1  | <input type="checkbox"/>            |
| Day 2  | <input type="checkbox"/>            |
| Day 3  | <input type="checkbox"/>            |
| Day 4  | <input type="checkbox"/>            |
| Day 5  | <input checked="" type="checkbox"/> |
| Day 6  | <input type="checkbox"/>            |
| Day 7  | <input type="checkbox"/>            |
| Day 8  | <input type="checkbox"/>            |
| Day 9  | <input type="checkbox"/>            |
| Day 10 | <input type="checkbox"/>            |
| Day 11 | <input type="checkbox"/>            |
| Day 12 | <input type="checkbox"/>            |
| Day 13 | <input type="checkbox"/>            |
| Day 14 | <input type="checkbox"/>            |
| Day 15 | <input type="checkbox"/>            |
| Day 16 | <input type="checkbox"/>            |
| Day 17 | <input type="checkbox"/>            |
| Day 18 | <input type="checkbox"/>            |
| Day 19 | <input type="checkbox"/>            |
| Day 20 | <input type="checkbox"/>            |
| Day 21 | <input type="checkbox"/>            |
| Day 22 | <input type="checkbox"/>            |
| Day 23 | <input type="checkbox"/>            |
| Day 24 | <input type="checkbox"/>            |
| Day 25 | <input type="checkbox"/>            |
| Day 26 | <input type="checkbox"/>            |
| Day 27 | <input type="checkbox"/>            |
| Day 28 | <input type="checkbox"/>            |
| Day 29 | <input type="checkbox"/>            |
| Day 30 | <input type="checkbox"/>            |
| Day 31 | <input type="checkbox"/>            |
| Day 32 | <input type="checkbox"/>            |
| Day 33 | <input type="checkbox"/>            |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:15:04

|                      |             |                                     |
|----------------------|-------------|-------------------------------------|
|                      | Day 34      | <input type="checkbox"/>            |
|                      | Day 35      | <input type="checkbox"/>            |
|                      | Day 36      | <input type="checkbox"/>            |
|                      | Day 37      | <input type="checkbox"/>            |
|                      | Day 38      | <input type="checkbox"/>            |
|                      | Day 39      | <input type="checkbox"/>            |
|                      | Day 40      | <input type="checkbox"/>            |
| Date                 | 03 NOV 2020 |                                     |
| Assessment Not Done  | False       |                                     |
| O2 Saturation        |             |                                     |
| O2 Saturation Units  |             |                                     |
| Temperature          |             |                                     |
| Chills               | None        | <input type="checkbox"/>            |
|                      | Mild        | <input checked="" type="checkbox"/> |
|                      | Moderate    | <input type="checkbox"/>            |
|                      | Severe      | <input type="checkbox"/>            |
|                      | Not Done    | <input type="checkbox"/>            |
| Cough                | None        | <input checked="" type="checkbox"/> |
|                      | Mild        | <input type="checkbox"/>            |
|                      | Moderate    | <input type="checkbox"/>            |
|                      | Severe      | <input type="checkbox"/>            |
|                      | Not Done    | <input type="checkbox"/>            |
| Shortness of Breath  | None        | <input checked="" type="checkbox"/> |
|                      | Mild        | <input type="checkbox"/>            |
|                      | Moderate    | <input type="checkbox"/>            |
|                      | Severe      | <input type="checkbox"/>            |
|                      | Not Done    | <input type="checkbox"/>            |
| Difficulty Breathing | None        | <input checked="" type="checkbox"/> |
|                      | Mild        | <input type="checkbox"/>            |
|                      | Moderate    | <input type="checkbox"/>            |
|                      | Severe      | <input type="checkbox"/>            |
|                      | Not Done    | <input type="checkbox"/>            |
| Fatigue              | None        | <input checked="" type="checkbox"/> |
| v6.020 DTW (1102)    | 327 of 2382 |                                     |



US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:15:04

|                        |          |                                  |
|------------------------|----------|----------------------------------|
|                        | Mild     | <input type="radio"/>            |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |
| <hr/>                  |          |                                  |
| Muscle Aches (Myalgia) | None     | <input checked="" type="radio"/> |
|                        | Mild     | <input type="radio"/>            |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |
| <hr/>                  |          |                                  |
| Body Aches             | None     | <input checked="" type="radio"/> |
|                        | Mild     | <input type="radio"/>            |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |
| <hr/>                  |          |                                  |
| Headache               | None     | <input type="radio"/>            |
|                        | Mild     | <input checked="" type="radio"/> |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |
| <hr/>                  |          |                                  |
| New Loss of Taste      | None     | <input checked="" type="radio"/> |
|                        | Mild     | <input type="radio"/>            |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |
| <hr/>                  |          |                                  |
| New Loss of Smell      | None     | <input checked="" type="radio"/> |
|                        | Mild     | <input type="radio"/>            |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |
| <hr/>                  |          |                                  |
| Nasal Congestion       | None     | <input checked="" type="radio"/> |
|                        | Mild     | <input type="radio"/>            |
|                        | Moderate | <input type="radio"/>            |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:15:04

|                         |          |                                     |
|-------------------------|----------|-------------------------------------|
|                         | Severe   | <input type="checkbox"/>            |
|                         | Not Done | <input type="checkbox"/>            |
| Runny Nose (Rhinorrhea) | None     | <input checked="" type="checkbox"/> |
|                         | Mild     | <input type="checkbox"/>            |
|                         | Moderate | <input type="checkbox"/>            |
|                         | Severe   | <input type="checkbox"/>            |
|                         | Not Done | <input type="checkbox"/>            |
| Nausea                  | None     | <input checked="" type="checkbox"/> |
|                         | Mild     | <input type="checkbox"/>            |
|                         | Moderate | <input type="checkbox"/>            |
|                         | Severe   | <input type="checkbox"/>            |
|                         | Not Done | <input type="checkbox"/>            |
| Vomiting                | None     | <input checked="" type="checkbox"/> |
|                         | Mild     | <input type="checkbox"/>            |
|                         | Moderate | <input type="checkbox"/>            |
|                         | Severe   | <input type="checkbox"/>            |
|                         | Not Done | <input type="checkbox"/>            |
| Diarrhea                | None     | <input checked="" type="checkbox"/> |
|                         | Mild     | <input type="checkbox"/>            |
|                         | Moderate | <input type="checkbox"/>            |
|                         | Severe   | <input type="checkbox"/>            |
|                         | Not Done | <input type="checkbox"/>            |
| Sore Throat             | None     | <input checked="" type="checkbox"/> |
|                         | Mild     | <input type="checkbox"/>            |
|                         | Moderate | <input type="checkbox"/>            |
|                         | Severe   | <input type="checkbox"/>            |
|                         | Not Done | <input type="checkbox"/>            |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:15:04

[Symptom Day](#)

|        |                                     |
|--------|-------------------------------------|
| Day 1  | <input type="checkbox"/>            |
| Day 2  | <input type="checkbox"/>            |
| Day 3  | <input type="checkbox"/>            |
| Day 4  | <input type="checkbox"/>            |
| Day 5  | <input type="checkbox"/>            |
| Day 6  | <input checked="" type="checkbox"/> |
| Day 7  | <input type="checkbox"/>            |
| Day 8  | <input type="checkbox"/>            |
| Day 9  | <input type="checkbox"/>            |
| Day 10 | <input type="checkbox"/>            |
| Day 11 | <input type="checkbox"/>            |
| Day 12 | <input type="checkbox"/>            |
| Day 13 | <input type="checkbox"/>            |
| Day 14 | <input type="checkbox"/>            |
| Day 15 | <input type="checkbox"/>            |
| Day 16 | <input type="checkbox"/>            |
| Day 17 | <input type="checkbox"/>            |
| Day 18 | <input type="checkbox"/>            |
| Day 19 | <input type="checkbox"/>            |
| Day 20 | <input type="checkbox"/>            |
| Day 21 | <input type="checkbox"/>            |
| Day 22 | <input type="checkbox"/>            |
| Day 23 | <input type="checkbox"/>            |
| Day 24 | <input type="checkbox"/>            |
| Day 25 | <input type="checkbox"/>            |
| Day 26 | <input type="checkbox"/>            |
| Day 27 | <input type="checkbox"/>            |
| Day 28 | <input type="checkbox"/>            |
| Day 29 | <input type="checkbox"/>            |
| Day 30 | <input type="checkbox"/>            |
| Day 31 | <input type="checkbox"/>            |
| Day 32 | <input type="checkbox"/>            |
| Day 33 | <input type="checkbox"/>            |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:15:04

|                      |             |                                     |
|----------------------|-------------|-------------------------------------|
|                      | Day 34      | <input type="checkbox"/>            |
|                      | Day 35      | <input type="checkbox"/>            |
|                      | Day 36      | <input type="checkbox"/>            |
|                      | Day 37      | <input type="checkbox"/>            |
|                      | Day 38      | <input type="checkbox"/>            |
|                      | Day 39      | <input type="checkbox"/>            |
|                      | Day 40      | <input type="checkbox"/>            |
| Date                 | 04 NOV 2020 |                                     |
| Assessment Not Done  | False       |                                     |
| O2 Saturation        |             |                                     |
| O2 Saturation Units  |             |                                     |
| Temperature          |             |                                     |
| Chills               | None        | <input type="checkbox"/>            |
|                      | Mild        | <input checked="" type="checkbox"/> |
|                      | Moderate    | <input type="checkbox"/>            |
|                      | Severe      | <input type="checkbox"/>            |
|                      | Not Done    | <input type="checkbox"/>            |
| Cough                | None        | <input checked="" type="checkbox"/> |
|                      | Mild        | <input type="checkbox"/>            |
|                      | Moderate    | <input type="checkbox"/>            |
|                      | Severe      | <input type="checkbox"/>            |
|                      | Not Done    | <input type="checkbox"/>            |
| Shortness of Breath  | None        | <input checked="" type="checkbox"/> |
|                      | Mild        | <input type="checkbox"/>            |
|                      | Moderate    | <input type="checkbox"/>            |
|                      | Severe      | <input type="checkbox"/>            |
|                      | Not Done    | <input type="checkbox"/>            |
| Difficulty Breathing | None        | <input checked="" type="checkbox"/> |
|                      | Mild        | <input type="checkbox"/>            |
|                      | Moderate    | <input type="checkbox"/>            |
|                      | Severe      | <input type="checkbox"/>            |
|                      | Not Done    | <input type="checkbox"/>            |
| Fatigue              | None        | <input checked="" type="checkbox"/> |
| v6.020 DTW (1102)    | 331 of 2382 |                                     |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:15:04

|                        |          |                                  |
|------------------------|----------|----------------------------------|
|                        | Mild     | <input type="radio"/>            |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |
| Muscle Aches (Myalgia) | None     | <input checked="" type="radio"/> |
|                        | Mild     | <input type="radio"/>            |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |
| Body Aches             | None     | <input checked="" type="radio"/> |
|                        | Mild     | <input type="radio"/>            |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |
| Headache               | None     | <input type="radio"/>            |
|                        | Mild     | <input checked="" type="radio"/> |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |
| New Loss of Taste      | None     | <input checked="" type="radio"/> |
|                        | Mild     | <input type="radio"/>            |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |
| New Loss of Smell      | None     | <input checked="" type="radio"/> |
|                        | Mild     | <input type="radio"/>            |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |
| Nasal Congestion       | None     | <input checked="" type="radio"/> |
|                        | Mild     | <input type="radio"/>            |
|                        | Moderate | <input type="radio"/>            |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:15:04

|                         |          |                                     |
|-------------------------|----------|-------------------------------------|
|                         | Severe   | <input type="checkbox"/>            |
|                         | Not Done | <input type="checkbox"/>            |
| Runny Nose (Rhinorrhea) | None     | <input checked="" type="checkbox"/> |
|                         | Mild     | <input type="checkbox"/>            |
|                         | Moderate | <input type="checkbox"/>            |
|                         | Severe   | <input type="checkbox"/>            |
|                         | Not Done | <input type="checkbox"/>            |
| Nausea                  | None     | <input checked="" type="checkbox"/> |
|                         | Mild     | <input type="checkbox"/>            |
|                         | Moderate | <input type="checkbox"/>            |
|                         | Severe   | <input type="checkbox"/>            |
|                         | Not Done | <input type="checkbox"/>            |
| Vomiting                | None     | <input checked="" type="checkbox"/> |
|                         | Mild     | <input type="checkbox"/>            |
|                         | Moderate | <input type="checkbox"/>            |
|                         | Severe   | <input type="checkbox"/>            |
|                         | Not Done | <input type="checkbox"/>            |
| Diarrhea                | None     | <input checked="" type="checkbox"/> |
|                         | Mild     | <input type="checkbox"/>            |
|                         | Moderate | <input type="checkbox"/>            |
|                         | Severe   | <input type="checkbox"/>            |
|                         | Not Done | <input type="checkbox"/>            |
| Sore Throat             | None     | <input checked="" type="checkbox"/> |
|                         | Mild     | <input type="checkbox"/>            |
|                         | Moderate | <input type="checkbox"/>            |
|                         | Severe   | <input type="checkbox"/>            |
|                         | Not Done | <input type="checkbox"/>            |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:15:04

Symptom Day

|        |                                     |
|--------|-------------------------------------|
| Day 1  | <input type="checkbox"/>            |
| Day 2  | <input type="checkbox"/>            |
| Day 3  | <input type="checkbox"/>            |
| Day 4  | <input type="checkbox"/>            |
| Day 5  | <input type="checkbox"/>            |
| Day 6  | <input type="checkbox"/>            |
| Day 7  | <input checked="" type="checkbox"/> |
| Day 8  | <input type="checkbox"/>            |
| Day 9  | <input type="checkbox"/>            |
| Day 10 | <input type="checkbox"/>            |
| Day 11 | <input type="checkbox"/>            |
| Day 12 | <input type="checkbox"/>            |
| Day 13 | <input type="checkbox"/>            |
| Day 14 | <input type="checkbox"/>            |
| Day 15 | <input type="checkbox"/>            |
| Day 16 | <input type="checkbox"/>            |
| Day 17 | <input type="checkbox"/>            |
| Day 18 | <input type="checkbox"/>            |
| Day 19 | <input type="checkbox"/>            |
| Day 20 | <input type="checkbox"/>            |
| Day 21 | <input type="checkbox"/>            |
| Day 22 | <input type="checkbox"/>            |
| Day 23 | <input type="checkbox"/>            |
| Day 24 | <input type="checkbox"/>            |
| Day 25 | <input type="checkbox"/>            |
| Day 26 | <input type="checkbox"/>            |
| Day 27 | <input type="checkbox"/>            |
| Day 28 | <input type="checkbox"/>            |
| Day 29 | <input type="checkbox"/>            |
| Day 30 | <input type="checkbox"/>            |
| Day 31 | <input type="checkbox"/>            |
| Day 32 | <input type="checkbox"/>            |
| Day 33 | <input type="checkbox"/>            |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:15:04

|                      |             |                                  |
|----------------------|-------------|----------------------------------|
|                      | Day 34      | <input type="checkbox"/>         |
|                      | Day 35      | <input type="checkbox"/>         |
|                      | Day 36      | <input type="checkbox"/>         |
|                      | Day 37      | <input type="checkbox"/>         |
|                      | Day 38      | <input type="checkbox"/>         |
|                      | Day 39      | <input type="checkbox"/>         |
|                      | Day 40      | <input type="checkbox"/>         |
| Date                 | 05 NOV 2020 |                                  |
| Assessment Not Done  | False       |                                  |
| O2 Saturation        |             |                                  |
| O2 Saturation Units  |             |                                  |
| Temperature          |             |                                  |
| Chills               | None        | <input checked="" type="radio"/> |
|                      | Mild        | <input type="radio"/>            |
|                      | Moderate    | <input type="radio"/>            |
|                      | Severe      | <input type="radio"/>            |
|                      | Not Done    | <input type="radio"/>            |
| Cough                | None        | <input checked="" type="radio"/> |
|                      | Mild        | <input type="radio"/>            |
|                      | Moderate    | <input type="radio"/>            |
|                      | Severe      | <input type="radio"/>            |
|                      | Not Done    | <input type="radio"/>            |
| Shortness of Breath  | None        | <input checked="" type="radio"/> |
|                      | Mild        | <input type="radio"/>            |
|                      | Moderate    | <input type="radio"/>            |
|                      | Severe      | <input type="radio"/>            |
|                      | Not Done    | <input type="radio"/>            |
| Difficulty Breathing | None        | <input checked="" type="radio"/> |
|                      | Mild        | <input type="radio"/>            |
|                      | Moderate    | <input type="radio"/>            |
|                      | Severe      | <input type="radio"/>            |
|                      | Not Done    | <input type="radio"/>            |
| Fatigue              | None        | <input checked="" type="radio"/> |
| v6.020 DTW (1102)    | 335 of 2382 |                                  |



US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:15:04

|                        |          |                                  |
|------------------------|----------|----------------------------------|
|                        | Mild     | <input type="radio"/>            |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |
| Muscle Aches (Myalgia) | None     | <input checked="" type="radio"/> |
|                        | Mild     | <input type="radio"/>            |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |
| Body Aches             | None     | <input checked="" type="radio"/> |
|                        | Mild     | <input type="radio"/>            |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |
| Headache               | None     | <input type="radio"/>            |
|                        | Mild     | <input checked="" type="radio"/> |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |
| New Loss of Taste      | None     | <input checked="" type="radio"/> |
|                        | Mild     | <input type="radio"/>            |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |
| New Loss of Smell      | None     | <input checked="" type="radio"/> |
|                        | Mild     | <input type="radio"/>            |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |
| Nasal Congestion       | None     | <input checked="" type="radio"/> |
|                        | Mild     | <input type="radio"/>            |
|                        | Moderate | <input type="radio"/>            |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:15:04

|                         |          |                                     |
|-------------------------|----------|-------------------------------------|
|                         | Severe   | <input type="checkbox"/>            |
|                         | Not Done | <input type="checkbox"/>            |
| Runny Nose (Rhinorrhea) | None     | <input checked="" type="checkbox"/> |
|                         | Mild     | <input type="checkbox"/>            |
|                         | Moderate | <input type="checkbox"/>            |
|                         | Severe   | <input type="checkbox"/>            |
|                         | Not Done | <input type="checkbox"/>            |
| Nausea                  | None     | <input checked="" type="checkbox"/> |
|                         | Mild     | <input type="checkbox"/>            |
|                         | Moderate | <input type="checkbox"/>            |
|                         | Severe   | <input type="checkbox"/>            |
|                         | Not Done | <input type="checkbox"/>            |
| Vomiting                | None     | <input checked="" type="checkbox"/> |
|                         | Mild     | <input type="checkbox"/>            |
|                         | Moderate | <input type="checkbox"/>            |
|                         | Severe   | <input type="checkbox"/>            |
|                         | Not Done | <input type="checkbox"/>            |
| Diarrhea                | None     | <input checked="" type="checkbox"/> |
|                         | Mild     | <input type="checkbox"/>            |
|                         | Moderate | <input type="checkbox"/>            |
|                         | Severe   | <input type="checkbox"/>            |
|                         | Not Done | <input type="checkbox"/>            |
| Sore Throat             | None     | <input checked="" type="checkbox"/> |
|                         | Mild     | <input type="checkbox"/>            |
|                         | Moderate | <input type="checkbox"/>            |
|                         | Severe   | <input type="checkbox"/>            |
|                         | Not Done | <input type="checkbox"/>            |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:15:04

Symptom Day

|        |                                     |
|--------|-------------------------------------|
| Day 1  | <input type="checkbox"/>            |
| Day 2  | <input type="checkbox"/>            |
| Day 3  | <input type="checkbox"/>            |
| Day 4  | <input type="checkbox"/>            |
| Day 5  | <input type="checkbox"/>            |
| Day 6  | <input type="checkbox"/>            |
| Day 7  | <input type="checkbox"/>            |
| Day 8  | <input checked="" type="checkbox"/> |
| Day 9  | <input type="checkbox"/>            |
| Day 10 | <input type="checkbox"/>            |
| Day 11 | <input type="checkbox"/>            |
| Day 12 | <input type="checkbox"/>            |
| Day 13 | <input type="checkbox"/>            |
| Day 14 | <input type="checkbox"/>            |
| Day 15 | <input type="checkbox"/>            |
| Day 16 | <input type="checkbox"/>            |
| Day 17 | <input type="checkbox"/>            |
| Day 18 | <input type="checkbox"/>            |
| Day 19 | <input type="checkbox"/>            |
| Day 20 | <input type="checkbox"/>            |
| Day 21 | <input type="checkbox"/>            |
| Day 22 | <input type="checkbox"/>            |
| Day 23 | <input type="checkbox"/>            |
| Day 24 | <input type="checkbox"/>            |
| Day 25 | <input type="checkbox"/>            |
| Day 26 | <input type="checkbox"/>            |
| Day 27 | <input type="checkbox"/>            |
| Day 28 | <input type="checkbox"/>            |
| Day 29 | <input type="checkbox"/>            |
| Day 30 | <input type="checkbox"/>            |
| Day 31 | <input type="checkbox"/>            |
| Day 32 | <input type="checkbox"/>            |
| Day 33 | <input type="checkbox"/>            |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:15:04

|                      |             |                                  |
|----------------------|-------------|----------------------------------|
|                      | Day 34      | <input type="checkbox"/>         |
|                      | Day 35      | <input type="checkbox"/>         |
|                      | Day 36      | <input type="checkbox"/>         |
|                      | Day 37      | <input type="checkbox"/>         |
|                      | Day 38      | <input type="checkbox"/>         |
|                      | Day 39      | <input type="checkbox"/>         |
|                      | Day 40      | <input type="checkbox"/>         |
| Date                 | 06 NOV 2020 |                                  |
| Assessment Not Done  | False       |                                  |
| O2 Saturation        | 97 %        |                                  |
| O2 Saturation Units  | %           |                                  |
| Temperature          | 98.0 F      |                                  |
| Chills               | None        | <input checked="" type="radio"/> |
|                      | Mild        | <input type="radio"/>            |
|                      | Moderate    | <input type="radio"/>            |
|                      | Severe      | <input type="radio"/>            |
|                      | Not Done    | <input type="radio"/>            |
| Cough                | None        | <input checked="" type="radio"/> |
|                      | Mild        | <input type="radio"/>            |
|                      | Moderate    | <input type="radio"/>            |
|                      | Severe      | <input type="radio"/>            |
|                      | Not Done    | <input type="radio"/>            |
| Shortness of Breath  | None        | <input checked="" type="radio"/> |
|                      | Mild        | <input type="radio"/>            |
|                      | Moderate    | <input type="radio"/>            |
|                      | Severe      | <input type="radio"/>            |
|                      | Not Done    | <input type="radio"/>            |
| Difficulty Breathing | None        | <input checked="" type="radio"/> |
|                      | Mild        | <input type="radio"/>            |
|                      | Moderate    | <input type="radio"/>            |
|                      | Severe      | <input type="radio"/>            |
|                      | Not Done    | <input type="radio"/>            |
| Fatigue              | None        | <input checked="" type="radio"/> |
| v6.020 DTW (1102)    | 339 of 2382 |                                  |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:15:04

|                        |          |                                     |
|------------------------|----------|-------------------------------------|
|                        | Mild     | <input type="checkbox"/>            |
|                        | Moderate | <input type="checkbox"/>            |
|                        | Severe   | <input type="checkbox"/>            |
|                        | Not Done | <input type="checkbox"/>            |
| Muscle Aches (Myalgia) | None     | <input type="checkbox"/>            |
|                        | Mild     | <input checked="" type="checkbox"/> |
|                        | Moderate | <input type="checkbox"/>            |
|                        | Severe   | <input type="checkbox"/>            |
|                        | Not Done | <input type="checkbox"/>            |
| Body Aches             | None     | <input checked="" type="checkbox"/> |
|                        | Mild     | <input type="checkbox"/>            |
|                        | Moderate | <input type="checkbox"/>            |
|                        | Severe   | <input type="checkbox"/>            |
|                        | Not Done | <input type="checkbox"/>            |
| Headache               | None     | <input checked="" type="checkbox"/> |
|                        | Mild     | <input type="checkbox"/>            |
|                        | Moderate | <input type="checkbox"/>            |
|                        | Severe   | <input type="checkbox"/>            |
|                        | Not Done | <input type="checkbox"/>            |
| New Loss of Taste      | None     | <input checked="" type="checkbox"/> |
|                        | Mild     | <input type="checkbox"/>            |
|                        | Moderate | <input type="checkbox"/>            |
|                        | Severe   | <input type="checkbox"/>            |
|                        | Not Done | <input type="checkbox"/>            |
| New Loss of Smell      | None     | <input checked="" type="checkbox"/> |
|                        | Mild     | <input type="checkbox"/>            |
|                        | Moderate | <input type="checkbox"/>            |
|                        | Severe   | <input type="checkbox"/>            |
|                        | Not Done | <input type="checkbox"/>            |
| Nasal Congestion       | None     | <input checked="" type="checkbox"/> |
|                        | Mild     | <input type="checkbox"/>            |
|                        | Moderate | <input type="checkbox"/>            |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:15:04

|                         |          |                                     |
|-------------------------|----------|-------------------------------------|
|                         | Severe   | <input type="checkbox"/>            |
|                         | Not Done | <input type="checkbox"/>            |
| Runny Nose (Rhinorrhea) | None     | <input checked="" type="checkbox"/> |
|                         | Mild     | <input type="checkbox"/>            |
|                         | Moderate | <input type="checkbox"/>            |
|                         | Severe   | <input type="checkbox"/>            |
|                         | Not Done | <input type="checkbox"/>            |
| Nausea                  | None     | <input checked="" type="checkbox"/> |
|                         | Mild     | <input type="checkbox"/>            |
|                         | Moderate | <input type="checkbox"/>            |
|                         | Severe   | <input type="checkbox"/>            |
|                         | Not Done | <input type="checkbox"/>            |
| Vomiting                | None     | <input checked="" type="checkbox"/> |
|                         | Mild     | <input type="checkbox"/>            |
|                         | Moderate | <input type="checkbox"/>            |
|                         | Severe   | <input type="checkbox"/>            |
|                         | Not Done | <input type="checkbox"/>            |
| Diarrhea                | None     | <input checked="" type="checkbox"/> |
|                         | Mild     | <input type="checkbox"/>            |
|                         | Moderate | <input type="checkbox"/>            |
|                         | Severe   | <input type="checkbox"/>            |
|                         | Not Done | <input type="checkbox"/>            |
| Sore Throat             | None     | <input checked="" type="checkbox"/> |
|                         | Mild     | <input type="checkbox"/>            |
|                         | Moderate | <input type="checkbox"/>            |
|                         | Severe   | <input type="checkbox"/>            |
|                         | Not Done | <input type="checkbox"/>            |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:15:04

Symptom Day

|        |                                     |
|--------|-------------------------------------|
| Day 1  | <input type="checkbox"/>            |
| Day 2  | <input type="checkbox"/>            |
| Day 3  | <input type="checkbox"/>            |
| Day 4  | <input type="checkbox"/>            |
| Day 5  | <input type="checkbox"/>            |
| Day 6  | <input type="checkbox"/>            |
| Day 7  | <input type="checkbox"/>            |
| Day 8  | <input type="checkbox"/>            |
| Day 9  | <input checked="" type="checkbox"/> |
| Day 10 | <input type="checkbox"/>            |
| Day 11 | <input type="checkbox"/>            |
| Day 12 | <input type="checkbox"/>            |
| Day 13 | <input type="checkbox"/>            |
| Day 14 | <input type="checkbox"/>            |
| Day 15 | <input type="checkbox"/>            |
| Day 16 | <input type="checkbox"/>            |
| Day 17 | <input type="checkbox"/>            |
| Day 18 | <input type="checkbox"/>            |
| Day 19 | <input type="checkbox"/>            |
| Day 20 | <input type="checkbox"/>            |
| Day 21 | <input type="checkbox"/>            |
| Day 22 | <input type="checkbox"/>            |
| Day 23 | <input type="checkbox"/>            |
| Day 24 | <input type="checkbox"/>            |
| Day 25 | <input type="checkbox"/>            |
| Day 26 | <input type="checkbox"/>            |
| Day 27 | <input type="checkbox"/>            |
| Day 28 | <input type="checkbox"/>            |
| Day 29 | <input type="checkbox"/>            |
| Day 30 | <input type="checkbox"/>            |
| Day 31 | <input type="checkbox"/>            |
| Day 32 | <input type="checkbox"/>            |
| Day 33 | <input type="checkbox"/>            |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:15:04

|                      |             |                                  |
|----------------------|-------------|----------------------------------|
|                      | Day 34      | <input type="checkbox"/>         |
|                      | Day 35      | <input type="checkbox"/>         |
|                      | Day 36      | <input type="checkbox"/>         |
|                      | Day 37      | <input type="checkbox"/>         |
|                      | Day 38      | <input type="checkbox"/>         |
|                      | Day 39      | <input type="checkbox"/>         |
|                      | Day 40      | <input type="checkbox"/>         |
| Date                 | 07 NOV 2020 |                                  |
| Assessment Not Done  | False       |                                  |
| O2 Saturation        | 98 %        |                                  |
| O2 Saturation Units  | %           |                                  |
| Temperature          | 98.2 F      |                                  |
| Chills               | None        | <input checked="" type="radio"/> |
|                      | Mild        | <input type="radio"/>            |
|                      | Moderate    | <input type="radio"/>            |
|                      | Severe      | <input type="radio"/>            |
|                      | Not Done    | <input type="radio"/>            |
| Cough                | None        | <input checked="" type="radio"/> |
|                      | Mild        | <input type="radio"/>            |
|                      | Moderate    | <input type="radio"/>            |
|                      | Severe      | <input type="radio"/>            |
|                      | Not Done    | <input type="radio"/>            |
| Shortness of Breath  | None        | <input checked="" type="radio"/> |
|                      | Mild        | <input type="radio"/>            |
|                      | Moderate    | <input type="radio"/>            |
|                      | Severe      | <input type="radio"/>            |
|                      | Not Done    | <input type="radio"/>            |
| Difficulty Breathing | None        | <input checked="" type="radio"/> |
|                      | Mild        | <input type="radio"/>            |
|                      | Moderate    | <input type="radio"/>            |
|                      | Severe      | <input type="radio"/>            |
|                      | Not Done    | <input type="radio"/>            |
| Fatigue              | None        | <input checked="" type="radio"/> |
| v6.020 DTW (1102)    | 343 of 2382 |                                  |



US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:15:04

|                        |          |                                     |
|------------------------|----------|-------------------------------------|
|                        | Mild     | <input type="checkbox"/>            |
|                        | Moderate | <input type="checkbox"/>            |
|                        | Severe   | <input type="checkbox"/>            |
|                        | Not Done | <input type="checkbox"/>            |
| Muscle Aches (Myalgia) | None     | <input type="checkbox"/>            |
|                        | Mild     | <input checked="" type="checkbox"/> |
|                        | Moderate | <input type="checkbox"/>            |
|                        | Severe   | <input type="checkbox"/>            |
|                        | Not Done | <input type="checkbox"/>            |
| Body Aches             | None     | <input type="checkbox"/>            |
|                        | Mild     | <input checked="" type="checkbox"/> |
|                        | Moderate | <input type="checkbox"/>            |
|                        | Severe   | <input type="checkbox"/>            |
|                        | Not Done | <input type="checkbox"/>            |
| Headache               | None     | <input type="checkbox"/>            |
|                        | Mild     | <input checked="" type="checkbox"/> |
|                        | Moderate | <input type="checkbox"/>            |
|                        | Severe   | <input type="checkbox"/>            |
|                        | Not Done | <input type="checkbox"/>            |
| New Loss of Taste      | None     | <input checked="" type="checkbox"/> |
|                        | Mild     | <input type="checkbox"/>            |
|                        | Moderate | <input type="checkbox"/>            |
|                        | Severe   | <input type="checkbox"/>            |
|                        | Not Done | <input type="checkbox"/>            |
| New Loss of Smell      | None     | <input checked="" type="checkbox"/> |
|                        | Mild     | <input type="checkbox"/>            |
|                        | Moderate | <input type="checkbox"/>            |
|                        | Severe   | <input type="checkbox"/>            |
|                        | Not Done | <input type="checkbox"/>            |
| Nasal Congestion       | None     | <input checked="" type="checkbox"/> |
|                        | Mild     | <input type="checkbox"/>            |
|                        | Moderate | <input type="checkbox"/>            |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:15:04

|                         |          |                                     |
|-------------------------|----------|-------------------------------------|
|                         | Severe   | <input type="checkbox"/>            |
|                         | Not Done | <input type="checkbox"/>            |
| Runny Nose (Rhinorrhea) | None     | <input checked="" type="checkbox"/> |
|                         | Mild     | <input type="checkbox"/>            |
|                         | Moderate | <input type="checkbox"/>            |
|                         | Severe   | <input type="checkbox"/>            |
|                         | Not Done | <input type="checkbox"/>            |
| Nausea                  | None     | <input checked="" type="checkbox"/> |
|                         | Mild     | <input type="checkbox"/>            |
|                         | Moderate | <input type="checkbox"/>            |
|                         | Severe   | <input type="checkbox"/>            |
|                         | Not Done | <input type="checkbox"/>            |
| Vomiting                | None     | <input checked="" type="checkbox"/> |
|                         | Mild     | <input type="checkbox"/>            |
|                         | Moderate | <input type="checkbox"/>            |
|                         | Severe   | <input type="checkbox"/>            |
|                         | Not Done | <input type="checkbox"/>            |
| Diarrhea                | None     | <input checked="" type="checkbox"/> |
|                         | Mild     | <input type="checkbox"/>            |
|                         | Moderate | <input type="checkbox"/>            |
|                         | Severe   | <input type="checkbox"/>            |
|                         | Not Done | <input type="checkbox"/>            |
| Sore Throat             | None     | <input checked="" type="checkbox"/> |
|                         | Mild     | <input type="checkbox"/>            |
|                         | Moderate | <input type="checkbox"/>            |
|                         | Severe   | <input type="checkbox"/>            |
|                         | Not Done | <input type="checkbox"/>            |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:15:04

Symptom Day

|        |                                     |
|--------|-------------------------------------|
| Day 1  | <input type="checkbox"/>            |
| Day 2  | <input type="checkbox"/>            |
| Day 3  | <input type="checkbox"/>            |
| Day 4  | <input type="checkbox"/>            |
| Day 5  | <input type="checkbox"/>            |
| Day 6  | <input type="checkbox"/>            |
| Day 7  | <input type="checkbox"/>            |
| Day 8  | <input type="checkbox"/>            |
| Day 9  | <input type="checkbox"/>            |
| Day 10 | <input checked="" type="checkbox"/> |
| Day 11 | <input type="checkbox"/>            |
| Day 12 | <input type="checkbox"/>            |
| Day 13 | <input type="checkbox"/>            |
| Day 14 | <input type="checkbox"/>            |
| Day 15 | <input type="checkbox"/>            |
| Day 16 | <input type="checkbox"/>            |
| Day 17 | <input type="checkbox"/>            |
| Day 18 | <input type="checkbox"/>            |
| Day 19 | <input type="checkbox"/>            |
| Day 20 | <input type="checkbox"/>            |
| Day 21 | <input type="checkbox"/>            |
| Day 22 | <input type="checkbox"/>            |
| Day 23 | <input type="checkbox"/>            |
| Day 24 | <input type="checkbox"/>            |
| Day 25 | <input type="checkbox"/>            |
| Day 26 | <input type="checkbox"/>            |
| Day 27 | <input type="checkbox"/>            |
| Day 28 | <input type="checkbox"/>            |
| Day 29 | <input type="checkbox"/>            |
| Day 30 | <input type="checkbox"/>            |
| Day 31 | <input type="checkbox"/>            |
| Day 32 | <input type="checkbox"/>            |
| Day 33 | <input type="checkbox"/>            |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:15:04

|                      |             |                                  |
|----------------------|-------------|----------------------------------|
|                      | Day 34      | <input type="checkbox"/>         |
|                      | Day 35      | <input type="checkbox"/>         |
|                      | Day 36      | <input type="checkbox"/>         |
|                      | Day 37      | <input type="checkbox"/>         |
|                      | Day 38      | <input type="checkbox"/>         |
|                      | Day 39      | <input type="checkbox"/>         |
|                      | Day 40      | <input type="checkbox"/>         |
| Date                 | 08 NOV 2020 |                                  |
| Assessment Not Done  | False       |                                  |
| O2 Saturation        | 94 %        |                                  |
| O2 Saturation Units  | %           |                                  |
| Temperature          | 98.6 F      |                                  |
| Chills               | None        | <input checked="" type="radio"/> |
|                      | Mild        | <input type="radio"/>            |
|                      | Moderate    | <input type="radio"/>            |
|                      | Severe      | <input type="radio"/>            |
|                      | Not Done    | <input type="radio"/>            |
| Cough                | None        | <input checked="" type="radio"/> |
|                      | Mild        | <input type="radio"/>            |
|                      | Moderate    | <input type="radio"/>            |
|                      | Severe      | <input type="radio"/>            |
|                      | Not Done    | <input type="radio"/>            |
| Shortness of Breath  | None        | <input checked="" type="radio"/> |
|                      | Mild        | <input type="radio"/>            |
|                      | Moderate    | <input type="radio"/>            |
|                      | Severe      | <input type="radio"/>            |
|                      | Not Done    | <input type="radio"/>            |
| Difficulty Breathing | None        | <input checked="" type="radio"/> |
|                      | Mild        | <input type="radio"/>            |
|                      | Moderate    | <input type="radio"/>            |
|                      | Severe      | <input type="radio"/>            |
|                      | Not Done    | <input type="radio"/>            |
| Fatigue              | None        | <input checked="" type="radio"/> |
| v6.020 DTW (1102)    | 347 of 2382 |                                  |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:15:04

|                        |          |                                     |
|------------------------|----------|-------------------------------------|
|                        | Mild     | <input type="checkbox"/>            |
|                        | Moderate | <input type="checkbox"/>            |
|                        | Severe   | <input type="checkbox"/>            |
|                        | Not Done | <input type="checkbox"/>            |
| Muscle Aches (Myalgia) | None     | <input type="checkbox"/>            |
|                        | Mild     | <input checked="" type="checkbox"/> |
|                        | Moderate | <input type="checkbox"/>            |
|                        | Severe   | <input type="checkbox"/>            |
|                        | Not Done | <input type="checkbox"/>            |
| Body Aches             | None     | <input type="checkbox"/>            |
|                        | Mild     | <input type="checkbox"/>            |
|                        | Moderate | <input checked="" type="checkbox"/> |
|                        | Severe   | <input type="checkbox"/>            |
|                        | Not Done | <input type="checkbox"/>            |
| Headache               | None     | <input type="checkbox"/>            |
|                        | Mild     | <input checked="" type="checkbox"/> |
|                        | Moderate | <input type="checkbox"/>            |
|                        | Severe   | <input type="checkbox"/>            |
|                        | Not Done | <input type="checkbox"/>            |
| New Loss of Taste      | None     | <input checked="" type="checkbox"/> |
|                        | Mild     | <input type="checkbox"/>            |
|                        | Moderate | <input type="checkbox"/>            |
|                        | Severe   | <input type="checkbox"/>            |
|                        | Not Done | <input type="checkbox"/>            |
| New Loss of Smell      | None     | <input checked="" type="checkbox"/> |
|                        | Mild     | <input type="checkbox"/>            |
|                        | Moderate | <input type="checkbox"/>            |
|                        | Severe   | <input type="checkbox"/>            |
|                        | Not Done | <input type="checkbox"/>            |
| Nasal Congestion       | None     | <input checked="" type="checkbox"/> |
|                        | Mild     | <input type="checkbox"/>            |
|                        | Moderate | <input type="checkbox"/>            |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:15:04

|                         |          |                                     |
|-------------------------|----------|-------------------------------------|
|                         | Severe   | <input type="checkbox"/>            |
|                         | Not Done | <input type="checkbox"/>            |
| Runny Nose (Rhinorrhea) | None     | <input checked="" type="checkbox"/> |
|                         | Mild     | <input type="checkbox"/>            |
|                         | Moderate | <input type="checkbox"/>            |
|                         | Severe   | <input type="checkbox"/>            |
|                         | Not Done | <input type="checkbox"/>            |
| Nausea                  | None     | <input checked="" type="checkbox"/> |
|                         | Mild     | <input type="checkbox"/>            |
|                         | Moderate | <input type="checkbox"/>            |
|                         | Severe   | <input type="checkbox"/>            |
|                         | Not Done | <input type="checkbox"/>            |
| Vomiting                | None     | <input checked="" type="checkbox"/> |
|                         | Mild     | <input type="checkbox"/>            |
|                         | Moderate | <input type="checkbox"/>            |
|                         | Severe   | <input type="checkbox"/>            |
|                         | Not Done | <input type="checkbox"/>            |
| Diarrhea                | None     | <input checked="" type="checkbox"/> |
|                         | Mild     | <input type="checkbox"/>            |
|                         | Moderate | <input type="checkbox"/>            |
|                         | Severe   | <input type="checkbox"/>            |
|                         | Not Done | <input type="checkbox"/>            |
| Sore Throat             | None     | <input checked="" type="checkbox"/> |
|                         | Mild     | <input type="checkbox"/>            |
|                         | Moderate | <input type="checkbox"/>            |
|                         | Severe   | <input type="checkbox"/>            |
|                         | Not Done | <input type="checkbox"/>            |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:15:04

Symptom Day

|        |                                     |
|--------|-------------------------------------|
| Day 1  | <input type="checkbox"/>            |
| Day 2  | <input type="checkbox"/>            |
| Day 3  | <input type="checkbox"/>            |
| Day 4  | <input type="checkbox"/>            |
| Day 5  | <input type="checkbox"/>            |
| Day 6  | <input type="checkbox"/>            |
| Day 7  | <input type="checkbox"/>            |
| Day 8  | <input type="checkbox"/>            |
| Day 9  | <input type="checkbox"/>            |
| Day 10 | <input type="checkbox"/>            |
| Day 11 | <input checked="" type="checkbox"/> |
| Day 12 | <input type="checkbox"/>            |
| Day 13 | <input type="checkbox"/>            |
| Day 14 | <input type="checkbox"/>            |
| Day 15 | <input type="checkbox"/>            |
| Day 16 | <input type="checkbox"/>            |
| Day 17 | <input type="checkbox"/>            |
| Day 18 | <input type="checkbox"/>            |
| Day 19 | <input type="checkbox"/>            |
| Day 20 | <input type="checkbox"/>            |
| Day 21 | <input type="checkbox"/>            |
| Day 22 | <input type="checkbox"/>            |
| Day 23 | <input type="checkbox"/>            |
| Day 24 | <input type="checkbox"/>            |
| Day 25 | <input type="checkbox"/>            |
| Day 26 | <input type="checkbox"/>            |
| Day 27 | <input type="checkbox"/>            |
| Day 28 | <input type="checkbox"/>            |
| Day 29 | <input type="checkbox"/>            |
| Day 30 | <input type="checkbox"/>            |
| Day 31 | <input type="checkbox"/>            |
| Day 32 | <input type="checkbox"/>            |
| Day 33 | <input type="checkbox"/>            |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:15:04

|                      |             |                                  |
|----------------------|-------------|----------------------------------|
|                      | Day 34      | <input type="checkbox"/>         |
|                      | Day 35      | <input type="checkbox"/>         |
|                      | Day 36      | <input type="checkbox"/>         |
|                      | Day 37      | <input type="checkbox"/>         |
|                      | Day 38      | <input type="checkbox"/>         |
|                      | Day 39      | <input type="checkbox"/>         |
|                      | Day 40      | <input type="checkbox"/>         |
| Date                 | 09 NOV 2020 |                                  |
| Assessment Not Done  | False       |                                  |
| O2 Saturation        | 98 %        |                                  |
| O2 Saturation Units  | %           |                                  |
| Temperature          | 98.1 F      |                                  |
| Chills               | None        | <input checked="" type="radio"/> |
|                      | Mild        | <input type="radio"/>            |
|                      | Moderate    | <input type="radio"/>            |
|                      | Severe      | <input type="radio"/>            |
|                      | Not Done    | <input type="radio"/>            |
| Cough                | None        | <input checked="" type="radio"/> |
|                      | Mild        | <input type="radio"/>            |
|                      | Moderate    | <input type="radio"/>            |
|                      | Severe      | <input type="radio"/>            |
|                      | Not Done    | <input type="radio"/>            |
| Shortness of Breath  | None        | <input checked="" type="radio"/> |
|                      | Mild        | <input type="radio"/>            |
|                      | Moderate    | <input type="radio"/>            |
|                      | Severe      | <input type="radio"/>            |
|                      | Not Done    | <input type="radio"/>            |
| Difficulty Breathing | None        | <input checked="" type="radio"/> |
|                      | Mild        | <input type="radio"/>            |
|                      | Moderate    | <input type="radio"/>            |
|                      | Severe      | <input type="radio"/>            |
|                      | Not Done    | <input type="radio"/>            |
| Fatigue              | None        | <input checked="" type="radio"/> |
| v6.020 DTW (1102)    | 351 of 2382 |                                  |



US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:15:04

|                        |          |                                     |
|------------------------|----------|-------------------------------------|
|                        | Mild     | <input type="checkbox"/>            |
|                        | Moderate | <input type="checkbox"/>            |
|                        | Severe   | <input type="checkbox"/>            |
|                        | Not Done | <input type="checkbox"/>            |
| Muscle Aches (Myalgia) | None     | <input type="checkbox"/>            |
|                        | Mild     | <input checked="" type="checkbox"/> |
|                        | Moderate | <input type="checkbox"/>            |
|                        | Severe   | <input type="checkbox"/>            |
|                        | Not Done | <input type="checkbox"/>            |
| Body Aches             | None     | <input type="checkbox"/>            |
|                        | Mild     | <input checked="" type="checkbox"/> |
|                        | Moderate | <input type="checkbox"/>            |
|                        | Severe   | <input type="checkbox"/>            |
|                        | Not Done | <input type="checkbox"/>            |
| Headache               | None     | <input type="checkbox"/>            |
|                        | Mild     | <input checked="" type="checkbox"/> |
|                        | Moderate | <input type="checkbox"/>            |
|                        | Severe   | <input type="checkbox"/>            |
|                        | Not Done | <input type="checkbox"/>            |
| New Loss of Taste      | None     | <input checked="" type="checkbox"/> |
|                        | Mild     | <input type="checkbox"/>            |
|                        | Moderate | <input type="checkbox"/>            |
|                        | Severe   | <input type="checkbox"/>            |
|                        | Not Done | <input type="checkbox"/>            |
| New Loss of Smell      | None     | <input checked="" type="checkbox"/> |
|                        | Mild     | <input type="checkbox"/>            |
|                        | Moderate | <input type="checkbox"/>            |
|                        | Severe   | <input type="checkbox"/>            |
|                        | Not Done | <input type="checkbox"/>            |
| Nasal Congestion       | None     | <input checked="" type="checkbox"/> |
|                        | Mild     | <input type="checkbox"/>            |
|                        | Moderate | <input type="checkbox"/>            |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:15:04

|                         |          |                                     |
|-------------------------|----------|-------------------------------------|
|                         | Severe   | <input type="checkbox"/>            |
|                         | Not Done | <input type="checkbox"/>            |
| Runny Nose (Rhinorrhea) | None     | <input checked="" type="checkbox"/> |
|                         | Mild     | <input type="checkbox"/>            |
|                         | Moderate | <input type="checkbox"/>            |
|                         | Severe   | <input type="checkbox"/>            |
|                         | Not Done | <input type="checkbox"/>            |
| Nausea                  | None     | <input checked="" type="checkbox"/> |
|                         | Mild     | <input type="checkbox"/>            |
|                         | Moderate | <input type="checkbox"/>            |
|                         | Severe   | <input type="checkbox"/>            |
|                         | Not Done | <input type="checkbox"/>            |
| Vomiting                | None     | <input checked="" type="checkbox"/> |
|                         | Mild     | <input type="checkbox"/>            |
|                         | Moderate | <input type="checkbox"/>            |
|                         | Severe   | <input type="checkbox"/>            |
|                         | Not Done | <input type="checkbox"/>            |
| Diarrhea                | None     | <input checked="" type="checkbox"/> |
|                         | Mild     | <input type="checkbox"/>            |
|                         | Moderate | <input type="checkbox"/>            |
|                         | Severe   | <input type="checkbox"/>            |
|                         | Not Done | <input type="checkbox"/>            |
| Sore Throat             | None     | <input checked="" type="checkbox"/> |
|                         | Mild     | <input type="checkbox"/>            |
|                         | Moderate | <input type="checkbox"/>            |
|                         | Severe   | <input type="checkbox"/>            |
|                         | Not Done | <input type="checkbox"/>            |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:15:04

[Symptom Day](#)

|        |                                     |
|--------|-------------------------------------|
| Day 1  | <input type="checkbox"/>            |
| Day 2  | <input type="checkbox"/>            |
| Day 3  | <input type="checkbox"/>            |
| Day 4  | <input type="checkbox"/>            |
| Day 5  | <input type="checkbox"/>            |
| Day 6  | <input type="checkbox"/>            |
| Day 7  | <input type="checkbox"/>            |
| Day 8  | <input type="checkbox"/>            |
| Day 9  | <input type="checkbox"/>            |
| Day 10 | <input type="checkbox"/>            |
| Day 11 | <input type="checkbox"/>            |
| Day 12 | <input checked="" type="checkbox"/> |
| Day 13 | <input type="checkbox"/>            |
| Day 14 | <input type="checkbox"/>            |
| Day 15 | <input type="checkbox"/>            |
| Day 16 | <input type="checkbox"/>            |
| Day 17 | <input type="checkbox"/>            |
| Day 18 | <input type="checkbox"/>            |
| Day 19 | <input type="checkbox"/>            |
| Day 20 | <input type="checkbox"/>            |
| Day 21 | <input type="checkbox"/>            |
| Day 22 | <input type="checkbox"/>            |
| Day 23 | <input type="checkbox"/>            |
| Day 24 | <input type="checkbox"/>            |
| Day 25 | <input type="checkbox"/>            |
| Day 26 | <input type="checkbox"/>            |
| Day 27 | <input type="checkbox"/>            |
| Day 28 | <input type="checkbox"/>            |
| Day 29 | <input type="checkbox"/>            |
| Day 30 | <input type="checkbox"/>            |
| Day 31 | <input type="checkbox"/>            |
| Day 32 | <input type="checkbox"/>            |
| Day 33 | <input type="checkbox"/>            |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:15:04

|                      |             |                                  |
|----------------------|-------------|----------------------------------|
|                      | Day 34      | <input type="checkbox"/>         |
|                      | Day 35      | <input type="checkbox"/>         |
|                      | Day 36      | <input type="checkbox"/>         |
|                      | Day 37      | <input type="checkbox"/>         |
|                      | Day 38      | <input type="checkbox"/>         |
|                      | Day 39      | <input type="checkbox"/>         |
|                      | Day 40      | <input type="checkbox"/>         |
| Date                 | 10 NOV 2020 |                                  |
| Assessment Not Done  | False       |                                  |
| O2 Saturation        | 97 %        |                                  |
| O2 Saturation Units  | %           |                                  |
| Temperature          | 98.4 F      |                                  |
| Chills               | None        | <input checked="" type="radio"/> |
|                      | Mild        | <input type="radio"/>            |
|                      | Moderate    | <input type="radio"/>            |
|                      | Severe      | <input type="radio"/>            |
|                      | Not Done    | <input type="radio"/>            |
| Cough                | None        | <input checked="" type="radio"/> |
|                      | Mild        | <input type="radio"/>            |
|                      | Moderate    | <input type="radio"/>            |
|                      | Severe      | <input type="radio"/>            |
|                      | Not Done    | <input type="radio"/>            |
| Shortness of Breath  | None        | <input checked="" type="radio"/> |
|                      | Mild        | <input type="radio"/>            |
|                      | Moderate    | <input type="radio"/>            |
|                      | Severe      | <input type="radio"/>            |
|                      | Not Done    | <input type="radio"/>            |
| Difficulty Breathing | None        | <input checked="" type="radio"/> |
|                      | Mild        | <input type="radio"/>            |
|                      | Moderate    | <input type="radio"/>            |
|                      | Severe      | <input type="radio"/>            |
|                      | Not Done    | <input type="radio"/>            |
| Fatigue              | None        | <input checked="" type="radio"/> |
| v6.020 DTW (1102)    | 355 of 2382 |                                  |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:15:04

|                        |          |                                     |
|------------------------|----------|-------------------------------------|
|                        | Mild     | <input type="checkbox"/>            |
|                        | Moderate | <input type="checkbox"/>            |
|                        | Severe   | <input type="checkbox"/>            |
|                        | Not Done | <input type="checkbox"/>            |
| Muscle Aches (Myalgia) | None     | <input type="checkbox"/>            |
|                        | Mild     | <input checked="" type="checkbox"/> |
|                        | Moderate | <input type="checkbox"/>            |
|                        | Severe   | <input type="checkbox"/>            |
|                        | Not Done | <input type="checkbox"/>            |
| Body Aches             | None     | <input type="checkbox"/>            |
|                        | Mild     | <input type="checkbox"/>            |
|                        | Moderate | <input checked="" type="checkbox"/> |
|                        | Severe   | <input type="checkbox"/>            |
|                        | Not Done | <input type="checkbox"/>            |
| Headache               | None     | <input type="checkbox"/>            |
|                        | Mild     | <input checked="" type="checkbox"/> |
|                        | Moderate | <input type="checkbox"/>            |
|                        | Severe   | <input type="checkbox"/>            |
|                        | Not Done | <input type="checkbox"/>            |
| New Loss of Taste      | None     | <input checked="" type="checkbox"/> |
|                        | Mild     | <input type="checkbox"/>            |
|                        | Moderate | <input type="checkbox"/>            |
|                        | Severe   | <input type="checkbox"/>            |
|                        | Not Done | <input type="checkbox"/>            |
| New Loss of Smell      | None     | <input checked="" type="checkbox"/> |
|                        | Mild     | <input type="checkbox"/>            |
|                        | Moderate | <input type="checkbox"/>            |
|                        | Severe   | <input type="checkbox"/>            |
|                        | Not Done | <input type="checkbox"/>            |
| Nasal Congestion       | None     | <input checked="" type="checkbox"/> |
|                        | Mild     | <input type="checkbox"/>            |
|                        | Moderate | <input type="checkbox"/>            |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:15:04

|                         |          |                                     |
|-------------------------|----------|-------------------------------------|
|                         | Severe   | <input type="checkbox"/>            |
|                         | Not Done | <input type="checkbox"/>            |
| Runny Nose (Rhinorrhea) | None     | <input checked="" type="checkbox"/> |
|                         | Mild     | <input type="checkbox"/>            |
|                         | Moderate | <input type="checkbox"/>            |
|                         | Severe   | <input type="checkbox"/>            |
|                         | Not Done | <input type="checkbox"/>            |
| Nausea                  | None     | <input checked="" type="checkbox"/> |
|                         | Mild     | <input type="checkbox"/>            |
|                         | Moderate | <input type="checkbox"/>            |
|                         | Severe   | <input type="checkbox"/>            |
|                         | Not Done | <input type="checkbox"/>            |
| Vomiting                | None     | <input checked="" type="checkbox"/> |
|                         | Mild     | <input type="checkbox"/>            |
|                         | Moderate | <input type="checkbox"/>            |
|                         | Severe   | <input type="checkbox"/>            |
|                         | Not Done | <input type="checkbox"/>            |
| Diarrhea                | None     | <input checked="" type="checkbox"/> |
|                         | Mild     | <input type="checkbox"/>            |
|                         | Moderate | <input type="checkbox"/>            |
|                         | Severe   | <input type="checkbox"/>            |
|                         | Not Done | <input type="checkbox"/>            |
| Sore Throat             | None     | <input checked="" type="checkbox"/> |
|                         | Mild     | <input type="checkbox"/>            |
|                         | Moderate | <input type="checkbox"/>            |
|                         | Severe   | <input type="checkbox"/>            |
|                         | Not Done | <input type="checkbox"/>            |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 11:15:04

Symptom Day

|        |                                     |
|--------|-------------------------------------|
| Day 1  | <input type="checkbox"/>            |
| Day 2  | <input type="checkbox"/>            |
| Day 3  | <input type="checkbox"/>            |
| Day 4  | <input type="checkbox"/>            |
| Day 5  | <input type="checkbox"/>            |
| Day 6  | <input type="checkbox"/>            |
| Day 7  | <input type="checkbox"/>            |
| Day 8  | <input type="checkbox"/>            |
| Day 9  | <input type="checkbox"/>            |
| Day 10 | <input type="checkbox"/>            |
| Day 11 | <input type="checkbox"/>            |
| Day 12 | <input type="checkbox"/>            |
| Day 13 | <input checked="" type="checkbox"/> |
| Day 14 | <input type="checkbox"/>            |
| Day 15 | <input type="checkbox"/>            |
| Day 16 | <input type="checkbox"/>            |
| Day 17 | <input type="checkbox"/>            |
| Day 18 | <input type="checkbox"/>            |
| Day 19 | <input type="checkbox"/>            |
| Day 20 | <input type="checkbox"/>            |
| Day 21 | <input type="checkbox"/>            |
| Day 22 | <input type="checkbox"/>            |
| Day 23 | <input type="checkbox"/>            |
| Day 24 | <input type="checkbox"/>            |
| Day 25 | <input type="checkbox"/>            |
| Day 26 | <input type="checkbox"/>            |
| Day 27 | <input type="checkbox"/>            |
| Day 28 | <input type="checkbox"/>            |
| Day 29 | <input type="checkbox"/>            |
| Day 30 | <input type="checkbox"/>            |
| Day 31 | <input type="checkbox"/>            |
| Day 32 | <input type="checkbox"/>            |
| Day 33 | <input type="checkbox"/>            |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 11:15:04

|                      |             |                                  |
|----------------------|-------------|----------------------------------|
|                      | Day 34      | <input type="checkbox"/>         |
|                      | Day 35      | <input type="checkbox"/>         |
|                      | Day 36      | <input type="checkbox"/>         |
|                      | Day 37      | <input type="checkbox"/>         |
|                      | Day 38      | <input type="checkbox"/>         |
|                      | Day 39      | <input type="checkbox"/>         |
|                      | Day 40      | <input type="checkbox"/>         |
| Date                 | 11 NOV 2020 |                                  |
| Assessment Not Done  | False       |                                  |
| O2 Saturation        | 98 %        |                                  |
| O2 Saturation Units  | %           |                                  |
| Temperature          | 98.3 F      |                                  |
| Chills               | None        | <input checked="" type="radio"/> |
|                      | Mild        | <input type="radio"/>            |
|                      | Moderate    | <input type="radio"/>            |
|                      | Severe      | <input type="radio"/>            |
|                      | Not Done    | <input type="radio"/>            |
| Cough                | None        | <input checked="" type="radio"/> |
|                      | Mild        | <input type="radio"/>            |
|                      | Moderate    | <input type="radio"/>            |
|                      | Severe      | <input type="radio"/>            |
|                      | Not Done    | <input type="radio"/>            |
| Shortness of Breath  | None        | <input checked="" type="radio"/> |
|                      | Mild        | <input type="radio"/>            |
|                      | Moderate    | <input type="radio"/>            |
|                      | Severe      | <input type="radio"/>            |
|                      | Not Done    | <input type="radio"/>            |
| Difficulty Breathing | None        | <input checked="" type="radio"/> |
|                      | Mild        | <input type="radio"/>            |
|                      | Moderate    | <input type="radio"/>            |
|                      | Severe      | <input type="radio"/>            |
|                      | Not Done    | <input type="radio"/>            |
| Fatigue              | None        | <input checked="" type="radio"/> |
| v6.020 DTW (1102)    | 359 of 2382 |                                  |



US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 11:15:04

|                        |          |                                     |
|------------------------|----------|-------------------------------------|
|                        | Mild     | <input type="checkbox"/>            |
|                        | Moderate | <input type="checkbox"/>            |
|                        | Severe   | <input type="checkbox"/>            |
|                        | Not Done | <input type="checkbox"/>            |
| Muscle Aches (Myalgia) | None     | <input type="checkbox"/>            |
|                        | Mild     | <input checked="" type="checkbox"/> |
|                        | Moderate | <input type="checkbox"/>            |
|                        | Severe   | <input type="checkbox"/>            |
|                        | Not Done | <input type="checkbox"/>            |
| Body Aches             | None     | <input type="checkbox"/>            |
|                        | Mild     | <input checked="" type="checkbox"/> |
|                        | Moderate | <input type="checkbox"/>            |
|                        | Severe   | <input type="checkbox"/>            |
|                        | Not Done | <input type="checkbox"/>            |
| Headache               | None     | <input checked="" type="checkbox"/> |
|                        | Mild     | <input type="checkbox"/>            |
|                        | Moderate | <input type="checkbox"/>            |
|                        | Severe   | <input type="checkbox"/>            |
|                        | Not Done | <input type="checkbox"/>            |
| New Loss of Taste      | None     | <input checked="" type="checkbox"/> |
|                        | Mild     | <input type="checkbox"/>            |
|                        | Moderate | <input type="checkbox"/>            |
|                        | Severe   | <input type="checkbox"/>            |
|                        | Not Done | <input type="checkbox"/>            |
| New Loss of Smell      | None     | <input checked="" type="checkbox"/> |
|                        | Mild     | <input type="checkbox"/>            |
|                        | Moderate | <input type="checkbox"/>            |
|                        | Severe   | <input type="checkbox"/>            |
|                        | Not Done | <input type="checkbox"/>            |
| Nasal Congestion       | None     | <input checked="" type="checkbox"/> |
|                        | Mild     | <input type="checkbox"/>            |
|                        | Moderate | <input type="checkbox"/>            |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 11:15:04

|                         |          |                                     |
|-------------------------|----------|-------------------------------------|
|                         | Severe   | <input type="checkbox"/>            |
|                         | Not Done | <input type="checkbox"/>            |
| Runny Nose (Rhinorrhea) | None     | <input checked="" type="checkbox"/> |
|                         | Mild     | <input type="checkbox"/>            |
|                         | Moderate | <input type="checkbox"/>            |
|                         | Severe   | <input type="checkbox"/>            |
|                         | Not Done | <input type="checkbox"/>            |
| Nausea                  | None     | <input checked="" type="checkbox"/> |
|                         | Mild     | <input type="checkbox"/>            |
|                         | Moderate | <input type="checkbox"/>            |
|                         | Severe   | <input type="checkbox"/>            |
|                         | Not Done | <input type="checkbox"/>            |
| Vomiting                | None     | <input checked="" type="checkbox"/> |
|                         | Mild     | <input type="checkbox"/>            |
|                         | Moderate | <input type="checkbox"/>            |
|                         | Severe   | <input type="checkbox"/>            |
|                         | Not Done | <input type="checkbox"/>            |
| Diarrhea                | None     | <input checked="" type="checkbox"/> |
|                         | Mild     | <input type="checkbox"/>            |
|                         | Moderate | <input type="checkbox"/>            |
|                         | Severe   | <input type="checkbox"/>            |
|                         | Not Done | <input type="checkbox"/>            |
| Sore Throat             | None     | <input checked="" type="checkbox"/> |
|                         | Mild     | <input type="checkbox"/>            |
|                         | Moderate | <input type="checkbox"/>            |
|                         | Severe   | <input type="checkbox"/>            |
|                         | Not Done | <input type="checkbox"/>            |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 11:15:04

[Symptom Day](#)

|        |                                     |
|--------|-------------------------------------|
| Day 1  | <input type="checkbox"/>            |
| Day 2  | <input type="checkbox"/>            |
| Day 3  | <input type="checkbox"/>            |
| Day 4  | <input type="checkbox"/>            |
| Day 5  | <input type="checkbox"/>            |
| Day 6  | <input type="checkbox"/>            |
| Day 7  | <input type="checkbox"/>            |
| Day 8  | <input type="checkbox"/>            |
| Day 9  | <input type="checkbox"/>            |
| Day 10 | <input type="checkbox"/>            |
| Day 11 | <input type="checkbox"/>            |
| Day 12 | <input type="checkbox"/>            |
| Day 13 | <input type="checkbox"/>            |
| Day 14 | <input checked="" type="checkbox"/> |
| Day 15 | <input type="checkbox"/>            |
| Day 16 | <input type="checkbox"/>            |
| Day 17 | <input type="checkbox"/>            |
| Day 18 | <input type="checkbox"/>            |
| Day 19 | <input type="checkbox"/>            |
| Day 20 | <input type="checkbox"/>            |
| Day 21 | <input type="checkbox"/>            |
| Day 22 | <input type="checkbox"/>            |
| Day 23 | <input type="checkbox"/>            |
| Day 24 | <input type="checkbox"/>            |
| Day 25 | <input type="checkbox"/>            |
| Day 26 | <input type="checkbox"/>            |
| Day 27 | <input type="checkbox"/>            |
| Day 28 | <input type="checkbox"/>            |
| Day 29 | <input type="checkbox"/>            |
| Day 30 | <input type="checkbox"/>            |
| Day 31 | <input type="checkbox"/>            |
| Day 32 | <input type="checkbox"/>            |
| Day 33 | <input type="checkbox"/>            |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 11:15:04

|                      |             |                                  |
|----------------------|-------------|----------------------------------|
|                      | Day 34      | <input type="checkbox"/>         |
|                      | Day 35      | <input type="checkbox"/>         |
|                      | Day 36      | <input type="checkbox"/>         |
|                      | Day 37      | <input type="checkbox"/>         |
|                      | Day 38      | <input type="checkbox"/>         |
|                      | Day 39      | <input type="checkbox"/>         |
|                      | Day 40      | <input type="checkbox"/>         |
| Date                 | 12 NOV 2020 |                                  |
| Assessment Not Done  | False       |                                  |
| O2 Saturation        | 98 %        |                                  |
| O2 Saturation Units  | %           |                                  |
| Temperature          | 98.5 F      |                                  |
| Chills               | None        | <input checked="" type="radio"/> |
|                      | Mild        | <input type="radio"/>            |
|                      | Moderate    | <input type="radio"/>            |
|                      | Severe      | <input type="radio"/>            |
|                      | Not Done    | <input type="radio"/>            |
| Cough                | None        | <input checked="" type="radio"/> |
|                      | Mild        | <input type="radio"/>            |
|                      | Moderate    | <input type="radio"/>            |
|                      | Severe      | <input type="radio"/>            |
|                      | Not Done    | <input type="radio"/>            |
| Shortness of Breath  | None        | <input checked="" type="radio"/> |
|                      | Mild        | <input type="radio"/>            |
|                      | Moderate    | <input type="radio"/>            |
|                      | Severe      | <input type="radio"/>            |
|                      | Not Done    | <input type="radio"/>            |
| Difficulty Breathing | None        | <input checked="" type="radio"/> |
|                      | Mild        | <input type="radio"/>            |
|                      | Moderate    | <input type="radio"/>            |
|                      | Severe      | <input type="radio"/>            |
|                      | Not Done    | <input type="radio"/>            |
| Fatigue              | None        | <input checked="" type="radio"/> |
| v6.020 DTW (1102)    | 363 of 2382 |                                  |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 11:15:04

|                        |          |                                     |
|------------------------|----------|-------------------------------------|
|                        | Mild     | <input type="checkbox"/>            |
|                        | Moderate | <input type="checkbox"/>            |
|                        | Severe   | <input type="checkbox"/>            |
|                        | Not Done | <input type="checkbox"/>            |
| Muscle Aches (Myalgia) | None     | <input type="checkbox"/>            |
|                        | Mild     | <input checked="" type="checkbox"/> |
|                        | Moderate | <input type="checkbox"/>            |
|                        | Severe   | <input type="checkbox"/>            |
|                        | Not Done | <input type="checkbox"/>            |
| Body Aches             | None     | <input type="checkbox"/>            |
|                        | Mild     | <input checked="" type="checkbox"/> |
|                        | Moderate | <input type="checkbox"/>            |
|                        | Severe   | <input type="checkbox"/>            |
|                        | Not Done | <input type="checkbox"/>            |
| Headache               | None     | <input checked="" type="checkbox"/> |
|                        | Mild     | <input type="checkbox"/>            |
|                        | Moderate | <input type="checkbox"/>            |
|                        | Severe   | <input type="checkbox"/>            |
|                        | Not Done | <input type="checkbox"/>            |
| New Loss of Taste      | None     | <input checked="" type="checkbox"/> |
|                        | Mild     | <input type="checkbox"/>            |
|                        | Moderate | <input type="checkbox"/>            |
|                        | Severe   | <input type="checkbox"/>            |
|                        | Not Done | <input type="checkbox"/>            |
| New Loss of Smell      | None     | <input checked="" type="checkbox"/> |
|                        | Mild     | <input type="checkbox"/>            |
|                        | Moderate | <input type="checkbox"/>            |
|                        | Severe   | <input type="checkbox"/>            |
|                        | Not Done | <input type="checkbox"/>            |
| Nasal Congestion       | None     | <input checked="" type="checkbox"/> |
|                        | Mild     | <input type="checkbox"/>            |
|                        | Moderate | <input type="checkbox"/>            |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 11:15:04

|                         |          |                                     |
|-------------------------|----------|-------------------------------------|
|                         | Severe   | <input type="checkbox"/>            |
|                         | Not Done | <input type="checkbox"/>            |
| Runny Nose (Rhinorrhea) | None     | <input checked="" type="checkbox"/> |
|                         | Mild     | <input type="checkbox"/>            |
|                         | Moderate | <input type="checkbox"/>            |
|                         | Severe   | <input type="checkbox"/>            |
|                         | Not Done | <input type="checkbox"/>            |
| Nausea                  | None     | <input checked="" type="checkbox"/> |
|                         | Mild     | <input type="checkbox"/>            |
|                         | Moderate | <input type="checkbox"/>            |
|                         | Severe   | <input type="checkbox"/>            |
|                         | Not Done | <input type="checkbox"/>            |
| Vomiting                | None     | <input checked="" type="checkbox"/> |
|                         | Mild     | <input type="checkbox"/>            |
|                         | Moderate | <input type="checkbox"/>            |
|                         | Severe   | <input type="checkbox"/>            |
|                         | Not Done | <input type="checkbox"/>            |
| Diarrhea                | None     | <input checked="" type="checkbox"/> |
|                         | Mild     | <input type="checkbox"/>            |
|                         | Moderate | <input type="checkbox"/>            |
|                         | Severe   | <input type="checkbox"/>            |
|                         | Not Done | <input type="checkbox"/>            |
| Sore Throat             | None     | <input checked="" type="checkbox"/> |
|                         | Mild     | <input type="checkbox"/>            |
|                         | Moderate | <input type="checkbox"/>            |
|                         | Severe   | <input type="checkbox"/>            |
|                         | Not Done | <input type="checkbox"/>            |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 11:15:04

[Symptom Day](#)

|        |                                     |
|--------|-------------------------------------|
| Day 1  | <input type="checkbox"/>            |
| Day 2  | <input type="checkbox"/>            |
| Day 3  | <input type="checkbox"/>            |
| Day 4  | <input type="checkbox"/>            |
| Day 5  | <input type="checkbox"/>            |
| Day 6  | <input type="checkbox"/>            |
| Day 7  | <input type="checkbox"/>            |
| Day 8  | <input type="checkbox"/>            |
| Day 9  | <input type="checkbox"/>            |
| Day 10 | <input type="checkbox"/>            |
| Day 11 | <input type="checkbox"/>            |
| Day 12 | <input type="checkbox"/>            |
| Day 13 | <input type="checkbox"/>            |
| Day 14 | <input type="checkbox"/>            |
| Day 15 | <input checked="" type="checkbox"/> |
| Day 16 | <input type="checkbox"/>            |
| Day 17 | <input type="checkbox"/>            |
| Day 18 | <input type="checkbox"/>            |
| Day 19 | <input type="checkbox"/>            |
| Day 20 | <input type="checkbox"/>            |
| Day 21 | <input type="checkbox"/>            |
| Day 22 | <input type="checkbox"/>            |
| Day 23 | <input type="checkbox"/>            |
| Day 24 | <input type="checkbox"/>            |
| Day 25 | <input type="checkbox"/>            |
| Day 26 | <input type="checkbox"/>            |
| Day 27 | <input type="checkbox"/>            |
| Day 28 | <input type="checkbox"/>            |
| Day 29 | <input type="checkbox"/>            |
| Day 30 | <input type="checkbox"/>            |
| Day 31 | <input type="checkbox"/>            |
| Day 32 | <input type="checkbox"/>            |
| Day 33 | <input type="checkbox"/>            |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 11:15:04

|                      |             |                                  |
|----------------------|-------------|----------------------------------|
|                      | Day 34      | <input type="checkbox"/>         |
|                      | Day 35      | <input type="checkbox"/>         |
|                      | Day 36      | <input type="checkbox"/>         |
|                      | Day 37      | <input type="checkbox"/>         |
|                      | Day 38      | <input type="checkbox"/>         |
|                      | Day 39      | <input type="checkbox"/>         |
|                      | Day 40      | <input type="checkbox"/>         |
| Date                 | 13 NOV 2020 |                                  |
| Assessment Not Done  | False       |                                  |
| O2 Saturation        | 98 %        |                                  |
| O2 Saturation Units  | %           |                                  |
| Temperature          | 98.3 F      |                                  |
| Chills               | None        | <input checked="" type="radio"/> |
|                      | Mild        | <input type="radio"/>            |
|                      | Moderate    | <input type="radio"/>            |
|                      | Severe      | <input type="radio"/>            |
|                      | Not Done    | <input type="radio"/>            |
| Cough                | None        | <input checked="" type="radio"/> |
|                      | Mild        | <input type="radio"/>            |
|                      | Moderate    | <input type="radio"/>            |
|                      | Severe      | <input type="radio"/>            |
|                      | Not Done    | <input type="radio"/>            |
| Shortness of Breath  | None        | <input checked="" type="radio"/> |
|                      | Mild        | <input type="radio"/>            |
|                      | Moderate    | <input type="radio"/>            |
|                      | Severe      | <input type="radio"/>            |
|                      | Not Done    | <input type="radio"/>            |
| Difficulty Breathing | None        | <input checked="" type="radio"/> |
|                      | Mild        | <input type="radio"/>            |
|                      | Moderate    | <input type="radio"/>            |
|                      | Severe      | <input type="radio"/>            |
|                      | Not Done    | <input type="radio"/>            |
| Fatigue              | None        | <input checked="" type="radio"/> |
| v6.020 DTW (1102)    | 367 of 2382 |                                  |



US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 11:15:04

|                        |          |                                     |
|------------------------|----------|-------------------------------------|
|                        | Mild     | <input type="checkbox"/>            |
|                        | Moderate | <input type="checkbox"/>            |
|                        | Severe   | <input type="checkbox"/>            |
|                        | Not Done | <input type="checkbox"/>            |
| Muscle Aches (Myalgia) | None     | <input type="checkbox"/>            |
|                        | Mild     | <input checked="" type="checkbox"/> |
|                        | Moderate | <input type="checkbox"/>            |
|                        | Severe   | <input type="checkbox"/>            |
|                        | Not Done | <input type="checkbox"/>            |
| Body Aches             | None     | <input type="checkbox"/>            |
|                        | Mild     | <input checked="" type="checkbox"/> |
|                        | Moderate | <input type="checkbox"/>            |
|                        | Severe   | <input type="checkbox"/>            |
|                        | Not Done | <input type="checkbox"/>            |
| Headache               | None     | <input checked="" type="checkbox"/> |
|                        | Mild     | <input type="checkbox"/>            |
|                        | Moderate | <input type="checkbox"/>            |
|                        | Severe   | <input type="checkbox"/>            |
|                        | Not Done | <input type="checkbox"/>            |
| New Loss of Taste      | None     | <input checked="" type="checkbox"/> |
|                        | Mild     | <input type="checkbox"/>            |
|                        | Moderate | <input type="checkbox"/>            |
|                        | Severe   | <input type="checkbox"/>            |
|                        | Not Done | <input type="checkbox"/>            |
| New Loss of Smell      | None     | <input checked="" type="checkbox"/> |
|                        | Mild     | <input type="checkbox"/>            |
|                        | Moderate | <input type="checkbox"/>            |
|                        | Severe   | <input type="checkbox"/>            |
|                        | Not Done | <input type="checkbox"/>            |
| Nasal Congestion       | None     | <input checked="" type="checkbox"/> |
|                        | Mild     | <input type="checkbox"/>            |
|                        | Moderate | <input type="checkbox"/>            |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 11:15:04

|                         |          |                                     |
|-------------------------|----------|-------------------------------------|
|                         | Severe   | <input type="checkbox"/>            |
|                         | Not Done | <input type="checkbox"/>            |
| Runny Nose (Rhinorrhea) | None     | <input checked="" type="checkbox"/> |
|                         | Mild     | <input type="checkbox"/>            |
|                         | Moderate | <input type="checkbox"/>            |
|                         | Severe   | <input type="checkbox"/>            |
|                         | Not Done | <input type="checkbox"/>            |
| Nausea                  | None     | <input checked="" type="checkbox"/> |
|                         | Mild     | <input type="checkbox"/>            |
|                         | Moderate | <input type="checkbox"/>            |
|                         | Severe   | <input type="checkbox"/>            |
|                         | Not Done | <input type="checkbox"/>            |
| Vomiting                | None     | <input checked="" type="checkbox"/> |
|                         | Mild     | <input type="checkbox"/>            |
|                         | Moderate | <input type="checkbox"/>            |
|                         | Severe   | <input type="checkbox"/>            |
|                         | Not Done | <input type="checkbox"/>            |
| Diarrhea                | None     | <input checked="" type="checkbox"/> |
|                         | Mild     | <input type="checkbox"/>            |
|                         | Moderate | <input type="checkbox"/>            |
|                         | Severe   | <input type="checkbox"/>            |
|                         | Not Done | <input type="checkbox"/>            |
| Sore Throat             | None     | <input checked="" type="checkbox"/> |
|                         | Mild     | <input type="checkbox"/>            |
|                         | Moderate | <input type="checkbox"/>            |
|                         | Severe   | <input type="checkbox"/>            |
|                         | Not Done | <input type="checkbox"/>            |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 11:15:04

|                                                                               |                                                                                                                                                              |
|-------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Date of Visit                                                                 | 06 NOV 2020                                                                                                                                                  |
| Was the Subject Tested For SARS-CoV-2 by RT-PCR?                              | Yes <input checked="" type="radio"/><br>No <input type="radio"/>                                                                                             |
| Did Subject Test Positive For SARS-CoV-2 by RT-PCR?                           | Yes <input type="radio"/><br>No <input checked="" type="radio"/>                                                                                             |
| Date of Test                                                                  | 06 NOV 2020                                                                                                                                                  |
| Type of Test Performed                                                        | Nasopharyngeal Swab <input checked="" type="radio"/><br>Nasal Swab <input type="radio"/><br>Saliva Test <input type="radio"/><br>Other <input type="radio"/> |
| Other, specify _____                                                          |                                                                                                                                                              |
| Was this diagnostic test performed at a lab other than the Study Central Lab? | Yes <input type="radio"/><br>No <input checked="" type="radio"/>                                                                                             |
| If yes, provide lab information below                                         |                                                                                                                                                              |
| Lab/ Institution Test Performed                                               | _____                                                                                                                                                        |
| CLIA Certified?                                                               | Yes <input type="radio"/><br>No <input type="radio"/>                                                                                                        |
| COVID-19 Positive (CSA Programming Field Only)                                | 0                                                                                                                                                            |

**US3742169**

**Folder: Covid-19 Assessment 06 Nov 2020**

**Form: Generate Next COVID-19 Assessment**

**Generated On: 26 Nov 2020 11:15:04**

---

Generate Next COVID-19 Assessment

Yes ☐

No ☐

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US3742169

Folder: Illness Visit (1)

Form: Saliva Collection

Generated On: 26 Nov 2020 11:15:04

| Visit  | Was Saliva Collected?  | Date of Collection |
|--------|------------------------|--------------------|
| Day 3  | Yes                    | 8 NOV 2020         |
| Day 5  | Yes                    | 10 NOV 2020        |
| Day 7  | Yes                    | 12 NOV 2020        |
| Day 9  | NA (COVID-19 Negative) |                    |
| Day 14 | NA (COVID-19 Negative) |                    |
| Day 21 | NA (COVID-19 Negative) |                    |
| Day 28 | NA (COVID-19 Negative) |                    |

US3742169

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:15:04

|                                                                 |                                         |
|-----------------------------------------------------------------|-----------------------------------------|
| Was this visit performed?                                       | Yes <input checked="" type="radio"/>    |
|                                                                 | No <input type="radio"/>                |
| Visit date (dd MMM yyyy)                                        | 06 NOV 2020                             |
| Was visit performed at the participant's home or at the clinic? | Home <input type="radio"/>              |
|                                                                 | Clinic <input checked="" type="radio"/> |
| Folder OID                                                      | SICKD1                                  |

US3742169

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:04

|                                     |                                       |
|-------------------------------------|---------------------------------------|
| Were vital signs assessed?          | Yes <input checked="" type="radio"/>  |
|                                     | No <input type="radio"/>              |
| Date of assessment (dd MMM yyyy)    | 06 NOV 2020                           |
| Time of assessment (00:00-23:59)    | 12:20 (24 HR)                         |
| Vital Signs Date and Time (derived) | 06 NOV 2020 12:20                     |
| Height (xxx.x)                      | 67.0 in                               |
| Weight (xxx.x)                      | 197.0 lb                              |
| Temperature (xxx.x)                 | 098.0 F                               |
| Route of measurement                | Oral <input checked="" type="radio"/> |
|                                     | Axillary <input type="radio"/>        |
|                                     | Other <input type="radio"/>           |
| If Other, specify                   |                                       |
| Pulse (xxx)                         | 063 beats/min                         |
| Pulse units                         | BPM                                   |
| Respiratory Rate (xxx)              | 14 breaths/min                        |
| Respiratory Rate units              | BREATHS/MIN                           |
| Systolic Blood Pressure (xxx)       | 124 mmHg                              |
| Systolic Blood Pressure units       | MMHG                                  |
| Diastolic Blood Pressure (xxx)      | 084 mmHg                              |
| Diastolic Blood Pressure units      | MMHG                                  |
| Height (derived)                    |                                       |
| Weight (derived)                    |                                       |

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Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:15:04

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

06 NOV 2020

*Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.*



US3742169

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 26 Nov 2020 11:15:04

Was Blood Sample Taken for Immunologic Assessment of  
SARS\_COV-2 Infection?

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

06 NOV 2020

**US3742169**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Visit Date**

**Generated On: 26 Nov 2020 11:15:04**

Was this visit performed? Yes ☐  
No ☐

Visit date (dd MMM yyyy) \_\_\_\_\_

Was visit performed at the participant's home or at the clinic? Home ☐  
Clinic ☐

Folder OID \_\_\_\_\_

US3742169

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:04

|                                           |                                   |
|-------------------------------------------|-----------------------------------|
| Were vital signs assessed?                | Yes <input type="checkbox"/>      |
|                                           | No <input type="checkbox"/>       |
| Date of assessment ( <i>dd MMM yyyy</i> ) |                                   |
| Time of assessment ( <i>00:00-23:59</i> ) |                                   |
| Vital Signs Date and Time (derived)       |                                   |
| Temperature ( <i>xxx.x</i> )              |                                   |
| Route of measurement                      | Oral <input type="checkbox"/>     |
|                                           | Axillary <input type="checkbox"/> |
|                                           | Other <input type="checkbox"/>    |
| If Other, specify                         |                                   |
| Pulse ( <i>xxx</i> )                      |                                   |
| Pulse units                               |                                   |
| Respiratory Rate ( <i>xxx</i> )           |                                   |
| Respiratory Rate units                    |                                   |
| Systolic Blood Pressure ( <i>xxx</i> )    |                                   |
| Systolic Blood Pressure units             |                                   |
| Diastolic Blood Pressure ( <i>xxx</i> )   |                                   |
| Diastolic Blood Pressure units            |                                   |
| Height (derived)                          |                                   |
| Weight (derived)                          |                                   |

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Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:15:04

Was the physical examination performed?

Yes ☐

No ☐

Date of examination (dd MMM yyyy)

*Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.*

US3742169

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 26 Nov 2020 11:15:04

Was Blood Sample Taken for Immunologic Assessment of  
SARS\_COV-2 Infection?

Yes ☐

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

US3742169

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 11:15:04

---

Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

---

US3742169

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:04

|                                                                |                                                                                                                                                                  |
|----------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| AEID                                                           |                                                                                                                                                                  |
| Adverse event                                                  | CONSTIPATION                                                                                                                                                     |
| Was this a medically-attended AE?                              | Yes <input type="radio"/><br>No <input checked="" type="radio"/>                                                                                                 |
| Was this a Solicited Adverse Reaction?                         | Yes <input type="radio"/><br>No <input checked="" type="radio"/>                                                                                                 |
| Is this event a confirmed diagnosis of Symptomatic Covid-19?   | Yes <input type="radio"/><br>No <input checked="" type="radio"/>                                                                                                 |
| Start date (dd MMM yyyy)                                       | 13 SEP 2020                                                                                                                                                      |
| Start time (00:00-23:59)                                       |                                                                                                                                                                  |
| AE start date and time (derived)                               |                                                                                                                                                                  |
| Ongoing?                                                       | Yes <input type="radio"/><br>No <input checked="" type="radio"/>                                                                                                 |
| If not Ongoing, end date (dd MMM yyyy)                         | 25 SEP 2020                                                                                                                                                      |
| End time (00:00-23:59)                                         |                                                                                                                                                                  |
| AE End Date and Time (derived)                                 |                                                                                                                                                                  |
| Severity                                                       | Grade 1/Mild <input type="radio"/><br>Grade 2/Moderate <input checked="" type="radio"/><br>Grade 3/Severe <input type="radio"/><br>Grade 4 <input type="radio"/> |
| Is the adverse event serious?                                  | Yes <input type="radio"/><br>No <input checked="" type="radio"/>                                                                                                 |
| AE is serious due To (check all that apply)                    |                                                                                                                                                                  |
| Death                                                          | False                                                                                                                                                            |
| Life threatening                                               | False                                                                                                                                                            |
| Requires inpatient or prolongation of existing Hospitalization | False                                                                                                                                                            |
| Hospital Admission Date (dd MMM yyyy)                          |                                                                                                                                                                  |
| Hospital Discharge Date (dd MMM yyyy)                          |                                                                                                                                                                  |
| Admitted to ICU?                                               | Yes <input type="radio"/><br>No <input type="radio"/><br>Unknown <input type="radio"/>                                                                           |
| Number of Days in ICU                                          |                                                                                                                                                                  |
| Persistent or significant disability or incapacity             | False                                                                                                                                                            |
| v6.020 DTW (1102)                                              | 382 of 2382                                                                                                                                                      |

US3742169

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:04

|                                                                                       |                                                                                                                                                                                                                                                                                 |
|---------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Congenital anomaly or birth defect                                                    | False                                                                                                                                                                                                                                                                           |
| Other medically important event                                                       | False                                                                                                                                                                                                                                                                           |
| Relationship to investigational product                                               | Not Related <input checked="" type="radio"/><br>Related <input type="radio"/><br>Not Applicable <input type="radio"/>                                                                                                                                                           |
| Relationship to Study Procedure                                                       | Not Related <input checked="" type="radio"/><br>Related <input type="radio"/><br>Not Applicable <input type="radio"/>                                                                                                                                                           |
| Action taken with investigational product                                             | None <input checked="" type="radio"/><br>Dose Delayed <input type="radio"/><br>Investigational Product Withdrawn <input type="radio"/><br>Not Applicable <input type="radio"/>                                                                                                  |
| Other action taken (check all that apply)                                             |                                                                                                                                                                                                                                                                                 |
| None                                                                                  | False                                                                                                                                                                                                                                                                           |
| Concomitant Medication                                                                | True                                                                                                                                                                                                                                                                            |
| Concomitant Procedure                                                                 | False                                                                                                                                                                                                                                                                           |
| Outcome                                                                               | Fatal <input type="radio"/><br>Not Recovered/Not Resolved <input type="radio"/><br>Recovered/Resolved <input checked="" type="radio"/><br>Recovered/Resolved with Sequelae <input type="radio"/><br>Recovering/Resolving <input type="radio"/><br>Unknown <input type="radio"/> |
| If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:<br>_____ |                                                                                                                                                                                                                                                                                 |
| Narrative<br>_____                                                                    |                                                                                                                                                                                                                                                                                 |
| Serious Adverse Event Derived (CSA Programming Field Only)                            | 0                                                                                                                                                                                                                                                                               |
| Medically Attended AE Derived (CSA Programming Field Only)                            | 0                                                                                                                                                                                                                                                                               |
| Admitted to ICU Derived (CSA Programming Field Only)                                  | _____                                                                                                                                                                                                                                                                           |



US3742169

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:15:04

|                                                                |                                                                                                                                                                  |
|----------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| AEID                                                           | USA-US127-2020-MRNA-1273-P30<br>1000003                                                                                                                          |
| Adverse event                                                  | RHEUMATOID ARTHRITIS                                                                                                                                             |
| Was this a medically-attended AE?                              | Yes <input checked="" type="radio"/><br>No <input type="radio"/>                                                                                                 |
| Was this a Solicited Adverse Reaction?                         | Yes <input type="radio"/><br>No <input checked="" type="radio"/>                                                                                                 |
| Is this event a confirmed diagnosis of Symptomatic Covid-19?   | Yes <input type="radio"/><br>No <input checked="" type="radio"/>                                                                                                 |
| Start date (dd MMM yyyy)                                       | 31 AUG 2020                                                                                                                                                      |
| Start time (00:00-23:59)                                       | 23:00 (24 HR)                                                                                                                                                    |
| AE start date and time (derived)                               | 31 AUG 2020 23:00                                                                                                                                                |
| Ongoing?                                                       | Yes <input checked="" type="radio"/><br>No <input type="radio"/>                                                                                                 |
| If not Ongoing, end date (dd MMM yyyy)                         |                                                                                                                                                                  |
| End time (00:00-23:59)                                         |                                                                                                                                                                  |
| AE End Date and Time (derived)                                 |                                                                                                                                                                  |
| Severity                                                       | Grade 1/Mild <input type="radio"/><br>Grade 2/Moderate <input checked="" type="radio"/><br>Grade 3/Severe <input type="radio"/><br>Grade 4 <input type="radio"/> |
| Is the adverse event serious?                                  | Yes <input checked="" type="radio"/><br>No <input type="radio"/>                                                                                                 |
| AE is serious due To (check all that apply)                    |                                                                                                                                                                  |
| Death                                                          | False                                                                                                                                                            |
| Life threatening                                               | False                                                                                                                                                            |
| Requires inpatient or prolongation of existing Hospitalization | False                                                                                                                                                            |
| Hospital Admission Date (dd MMM yyyy)                          |                                                                                                                                                                  |
| Hospital Discharge Date (dd MMM yyyy)                          |                                                                                                                                                                  |
| Admitted to ICU?                                               | Yes <input type="radio"/><br>No <input type="radio"/><br>Unknown <input type="radio"/>                                                                           |
| Number of Days in ICU                                          |                                                                                                                                                                  |
| v6.020 DTW (1102)                                              | 384 of 2382                                                                                                                                                      |

US3742169

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:15:04

|                                                                              |                                                                                                                                                                                                                                                                                 |
|------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Persistent or significant disability or incapacity                           | False                                                                                                                                                                                                                                                                           |
| Congenital anomaly or birth defect                                           | False                                                                                                                                                                                                                                                                           |
| Other medically important event                                              | True                                                                                                                                                                                                                                                                            |
| Relationship to investigational product                                      | Not Related <input type="radio"/><br>Related <input checked="" type="radio"/><br>Not Applicable <input type="radio"/>                                                                                                                                                           |
| Relationship to Study Procedure                                              | Not Related <input checked="" type="radio"/><br>Related <input type="radio"/><br>Not Applicable <input type="radio"/>                                                                                                                                                           |
| Action taken with investigational product                                    | None <input type="radio"/><br>Dose Delayed <input type="radio"/><br>Investigational Product <input checked="" type="radio"/><br>Withdrawn <input type="radio"/><br>Not Applicable <input type="radio"/>                                                                         |
| Other action taken (check all that apply)                                    |                                                                                                                                                                                                                                                                                 |
| None                                                                         | False                                                                                                                                                                                                                                                                           |
| Concomitant Medication                                                       | True                                                                                                                                                                                                                                                                            |
| Concomitant Procedure                                                        | False                                                                                                                                                                                                                                                                           |
| Outcome                                                                      | Fatal <input type="radio"/><br>Not Recovered/Not Resolved <input checked="" type="radio"/><br>Recovered/Resolved <input type="radio"/><br>Recovered/Resolved with Sequelae <input type="radio"/><br>Recovering/Resolving <input type="radio"/><br>Unknown <input type="radio"/> |
| If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: |                                                                                                                                                                                                                                                                                 |
| Narrative                                                                    |                                                                                                                                                                                                                                                                                 |

US3742169

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:15:04

AFTER FIRST VACCINATION, HE REPORTED IN THE E-DIARY MUSCLE AND JOINT ACHE/PAIN THROUGH DAY 7. MUSCLE AND JOINT ACHE/PAIN STARTED AGAIN ON SUNDAY THE 13TH OF SEPTEMBER, BUT WAS DOING BETTER BY TIME OF THE DAY 15 PHONE CALL ON THE 16TH OF SEPTEMBER. LATER THAT DAY, THE JOINT ACHE AND PAIN STARTED AGAIN AND CONTINUED. IT WAS IMPROVED WITH TYLENOL WHICH HE STOPPED TAKING ON THE 24TH OF SEPTEMBER. HE ALSO EXPERIENCED SOME TINNITUS, INSOMNIA AND CONSTIPATION POST VACCINATION. ON 9/29 HE WAS SEEN BY A RHEUMATOLOGIST WHO DIAGNOSED HIM WITH RHEUMATOID ARTHRITIS. SIGNIFICANT LABORATORY RESULTS RETURNED ON 02 OCTOBER 2020 AND INCLUDE RHEUMATOID FACTOR 62.5 IU/ML (NORMAL 0-13) AND ANTI-CCP AB >250 UNITS (NORMAL <20).

|                                                            |   |
|------------------------------------------------------------|---|
| Serious Adverse Event Derived (CSA Programming Field Only) | 1 |
| Medically Attended AE Derived (CSA Programming Field Only) | 1 |
| Admitted to ICU Derived (CSA Programming Field Only)       |   |

US3742169

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:15:04

|                                                                |                                                                                                                                                                  |
|----------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| AEID                                                           |                                                                                                                                                                  |
| Adverse event                                                  | TINNITUS                                                                                                                                                         |
| Was this a medically-attended AE?                              | Yes <input type="radio"/><br>No <input checked="" type="radio"/>                                                                                                 |
| Was this a Solicited Adverse Reaction?                         | Yes <input type="radio"/><br>No <input checked="" type="radio"/>                                                                                                 |
| Is this event a confirmed diagnosis of Symptomatic Covid-19?   | Yes <input type="radio"/><br>No <input checked="" type="radio"/>                                                                                                 |
| Start date (dd MMM yyyy)                                       | 20 SEP 2020                                                                                                                                                      |
| Start time (00:00-23:59)                                       |                                                                                                                                                                  |
| AE start date and time (derived)                               |                                                                                                                                                                  |
| Ongoing?                                                       | Yes <input type="radio"/><br>No <input checked="" type="radio"/>                                                                                                 |
| If not Ongoing, end date (dd MMM yyyy)                         | 22 SEP 2020                                                                                                                                                      |
| End time (00:00-23:59)                                         |                                                                                                                                                                  |
| AE End Date and Time (derived)                                 |                                                                                                                                                                  |
| Severity                                                       | Grade 1/Mild <input type="radio"/><br>Grade 2/Moderate <input checked="" type="radio"/><br>Grade 3/Severe <input type="radio"/><br>Grade 4 <input type="radio"/> |
| Is the adverse event serious?                                  | Yes <input type="radio"/><br>No <input checked="" type="radio"/>                                                                                                 |
| AE is serious due To (check all that apply)                    |                                                                                                                                                                  |
| Death                                                          | False                                                                                                                                                            |
| Life threatening                                               | False                                                                                                                                                            |
| Requires inpatient or prolongation of existing Hospitalization | False                                                                                                                                                            |
| Hospital Admission Date (dd MMM yyyy)                          |                                                                                                                                                                  |
| Hospital Discharge Date (dd MMM yyyy)                          |                                                                                                                                                                  |
| Admitted to ICU?                                               | Yes <input type="radio"/><br>No <input type="radio"/><br>Unknown <input type="radio"/>                                                                           |
| Number of Days in ICU                                          |                                                                                                                                                                  |
| Persistent or significant disability or incapacity             | False                                                                                                                                                            |
| v6.020 DTW (1102)                                              | 387 of 2382                                                                                                                                                      |

US3742169

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:15:04

|                                                                                       |                                                                                                                                                                                                                                                                                 |
|---------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Congenital anomaly or birth defect                                                    | False                                                                                                                                                                                                                                                                           |
| Other medically important event                                                       | False                                                                                                                                                                                                                                                                           |
| Relationship to investigational product                                               | Not Related <input checked="" type="radio"/><br>Related <input type="radio"/><br>Not Applicable <input type="radio"/>                                                                                                                                                           |
| Relationship to Study Procedure                                                       | Not Related <input checked="" type="radio"/><br>Related <input type="radio"/><br>Not Applicable <input type="radio"/>                                                                                                                                                           |
| Action taken with investigational product                                             | None <input checked="" type="radio"/><br>Dose Delayed <input type="radio"/><br>Investigational Product Withdrawn <input type="radio"/><br>Not Applicable <input type="radio"/>                                                                                                  |
| Other action taken (check all that apply)                                             |                                                                                                                                                                                                                                                                                 |
| None                                                                                  | True                                                                                                                                                                                                                                                                            |
| Concomitant Medication                                                                | False                                                                                                                                                                                                                                                                           |
| Concomitant Procedure                                                                 | False                                                                                                                                                                                                                                                                           |
| Outcome                                                                               | Fatal <input type="radio"/><br>Not Recovered/Not Resolved <input type="radio"/><br>Recovered/Resolved <input checked="" type="radio"/><br>Recovered/Resolved with Sequelae <input type="radio"/><br>Recovering/Resolving <input type="radio"/><br>Unknown <input type="radio"/> |
| If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:<br>_____ |                                                                                                                                                                                                                                                                                 |
| Narrative<br>_____                                                                    |                                                                                                                                                                                                                                                                                 |
| Serious Adverse Event Derived (CSA Programming Field Only)                            | 0                                                                                                                                                                                                                                                                               |
| Medically Attended AE Derived (CSA Programming Field Only)                            | 0                                                                                                                                                                                                                                                                               |
| Admitted to ICU Derived (CSA Programming Field Only)                                  | _____                                                                                                                                                                                                                                                                           |

US3742169

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:15:04

|                                                                |                                                                                                                                                                  |
|----------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| AEID                                                           |                                                                                                                                                                  |
| Adverse event                                                  | VOMITING                                                                                                                                                         |
| Was this a medically-attended AE?                              | Yes <input type="radio"/><br>No <input checked="" type="radio"/>                                                                                                 |
| Was this a Solicited Adverse Reaction?                         | Yes <input type="radio"/><br>No <input checked="" type="radio"/>                                                                                                 |
| Is this event a confirmed diagnosis of Symptomatic Covid-19?   | Yes <input type="radio"/><br>No <input checked="" type="radio"/>                                                                                                 |
| Start date (dd MMM yyyy)                                       | 19 SEP 2020                                                                                                                                                      |
| Start time (00:00-23:59)                                       |                                                                                                                                                                  |
| AE start date and time (derived)                               |                                                                                                                                                                  |
| Ongoing?                                                       | Yes <input type="radio"/><br>No <input checked="" type="radio"/>                                                                                                 |
| If not Ongoing, end date (dd MMM yyyy)                         | 20 SEP 2020                                                                                                                                                      |
| End time (00:00-23:59)                                         |                                                                                                                                                                  |
| AE End Date and Time (derived)                                 |                                                                                                                                                                  |
| Severity                                                       | Grade 1/Mild <input checked="" type="radio"/><br>Grade 2/Moderate <input type="radio"/><br>Grade 3/Severe <input type="radio"/><br>Grade 4 <input type="radio"/> |
| Is the adverse event serious?                                  | Yes <input type="radio"/><br>No <input checked="" type="radio"/>                                                                                                 |
| AE is serious due To (check all that apply)                    |                                                                                                                                                                  |
| Death                                                          | False                                                                                                                                                            |
| Life threatening                                               | False                                                                                                                                                            |
| Requires inpatient or prolongation of existing Hospitalization | False                                                                                                                                                            |
| Hospital Admission Date (dd MMM yyyy)                          |                                                                                                                                                                  |
| Hospital Discharge Date (dd MMM yyyy)                          |                                                                                                                                                                  |
| Admitted to ICU?                                               | Yes <input type="radio"/><br>No <input type="radio"/><br>Unknown <input type="radio"/>                                                                           |
| Number of Days in ICU                                          |                                                                                                                                                                  |
| Persistent or significant disability or incapacity             | False                                                                                                                                                            |
| v6.020 DTW (1102)                                              | 389 of 2382                                                                                                                                                      |

US3742169

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:15:04

|                                                                                       |                                                                                                                                                                                                                                                                                 |
|---------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Congenital anomaly or birth defect                                                    | False                                                                                                                                                                                                                                                                           |
| Other medically important event                                                       | False                                                                                                                                                                                                                                                                           |
| Relationship to investigational product                                               | Not Related <input checked="" type="radio"/><br>Related <input type="radio"/><br>Not Applicable <input type="radio"/>                                                                                                                                                           |
| Relationship to Study Procedure                                                       | Not Related <input checked="" type="radio"/><br>Related <input type="radio"/><br>Not Applicable <input type="radio"/>                                                                                                                                                           |
| Action taken with investigational product                                             | None <input checked="" type="radio"/><br>Dose Delayed <input type="radio"/><br>Investigational Product Withdrawn <input type="radio"/><br>Not Applicable <input type="radio"/>                                                                                                  |
| Other action taken (check all that apply)                                             |                                                                                                                                                                                                                                                                                 |
| None                                                                                  | True                                                                                                                                                                                                                                                                            |
| Concomitant Medication                                                                | False                                                                                                                                                                                                                                                                           |
| Concomitant Procedure                                                                 | False                                                                                                                                                                                                                                                                           |
| Outcome                                                                               | Fatal <input type="radio"/><br>Not Recovered/Not Resolved <input type="radio"/><br>Recovered/Resolved <input checked="" type="radio"/><br>Recovered/Resolved with Sequelae <input type="radio"/><br>Recovering/Resolving <input type="radio"/><br>Unknown <input type="radio"/> |
| If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:<br>_____ |                                                                                                                                                                                                                                                                                 |
| Narrative<br>_____                                                                    |                                                                                                                                                                                                                                                                                 |
| Serious Adverse Event Derived (CSA Programming Field Only)                            | 0                                                                                                                                                                                                                                                                               |
| Medically Attended AE Derived (CSA Programming Field Only)                            | 0                                                                                                                                                                                                                                                                               |
| Admitted to ICU Derived (CSA Programming Field Only)                                  | _____                                                                                                                                                                                                                                                                           |

US3742169

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:15:04

|                                                                |                                                                                                                                                                  |
|----------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| AEID                                                           |                                                                                                                                                                  |
| Adverse event                                                  | INSOMNIA                                                                                                                                                         |
| Was this a medically-attended AE?                              | Yes <input type="radio"/><br>No <input checked="" type="radio"/>                                                                                                 |
| Was this a Solicited Adverse Reaction?                         | Yes <input type="radio"/><br>No <input checked="" type="radio"/>                                                                                                 |
| Is this event a confirmed diagnosis of Symptomatic Covid-19?   | Yes <input type="radio"/><br>No <input checked="" type="radio"/>                                                                                                 |
| Start date (dd MMM yyyy)                                       | 7 SEP 2020                                                                                                                                                       |
| Start time (00:00-23:59)                                       |                                                                                                                                                                  |
| AE start date and time (derived)                               |                                                                                                                                                                  |
| Ongoing?                                                       | Yes <input type="radio"/><br>No <input checked="" type="radio"/>                                                                                                 |
| If not Ongoing, end date (dd MMM yyyy)                         | 25 SEP 2020                                                                                                                                                      |
| End time (00:00-23:59)                                         |                                                                                                                                                                  |
| AE End Date and Time (derived)                                 |                                                                                                                                                                  |
| Severity                                                       | Grade 1/Mild <input type="radio"/><br>Grade 2/Moderate <input checked="" type="radio"/><br>Grade 3/Severe <input type="radio"/><br>Grade 4 <input type="radio"/> |
| Is the adverse event serious?                                  | Yes <input type="radio"/><br>No <input checked="" type="radio"/>                                                                                                 |
| AE is serious due To (check all that apply)                    |                                                                                                                                                                  |
| Death                                                          | False                                                                                                                                                            |
| Life threatening                                               | False                                                                                                                                                            |
| Requires inpatient or prolongation of existing Hospitalization | False                                                                                                                                                            |
| Hospital Admission Date (dd MMM yyyy)                          |                                                                                                                                                                  |
| Hospital Discharge Date (dd MMM yyyy)                          |                                                                                                                                                                  |
| Admitted to ICU?                                               | Yes <input type="radio"/><br>No <input type="radio"/><br>Unknown <input type="radio"/>                                                                           |
| Number of Days in ICU                                          |                                                                                                                                                                  |
| Persistent or significant disability or incapacity             | False                                                                                                                                                            |
| v6.020 DTW (1102)                                              | 391 of 2382                                                                                                                                                      |



US3742169

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:15:04

|                                                                                       |                                                                                                                                                                                                                                                                                 |
|---------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Congenital anomaly or birth defect                                                    | False                                                                                                                                                                                                                                                                           |
| Other medically important event                                                       | False                                                                                                                                                                                                                                                                           |
| Relationship to investigational product                                               | Not Related <input checked="" type="radio"/><br>Related <input type="radio"/><br>Not Applicable <input type="radio"/>                                                                                                                                                           |
| Relationship to Study Procedure                                                       | Not Related <input checked="" type="radio"/><br>Related <input type="radio"/><br>Not Applicable <input type="radio"/>                                                                                                                                                           |
| Action taken with investigational product                                             | None <input checked="" type="radio"/><br>Dose Delayed <input type="radio"/><br>Investigational Product Withdrawn <input type="radio"/><br>Not Applicable <input type="radio"/>                                                                                                  |
| Other action taken (check all that apply)                                             |                                                                                                                                                                                                                                                                                 |
| None                                                                                  | True                                                                                                                                                                                                                                                                            |
| Concomitant Medication                                                                | False                                                                                                                                                                                                                                                                           |
| Concomitant Procedure                                                                 | False                                                                                                                                                                                                                                                                           |
| Outcome                                                                               | Fatal <input type="radio"/><br>Not Recovered/Not Resolved <input type="radio"/><br>Recovered/Resolved <input checked="" type="radio"/><br>Recovered/Resolved with Sequelae <input type="radio"/><br>Recovering/Resolving <input type="radio"/><br>Unknown <input type="radio"/> |
| If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:<br>_____ |                                                                                                                                                                                                                                                                                 |
| Narrative<br>_____                                                                    |                                                                                                                                                                                                                                                                                 |
| Serious Adverse Event Derived (CSA Programming Field Only)                            | 0                                                                                                                                                                                                                                                                               |
| Medically Attended AE Derived (CSA Programming Field Only)                            | 0                                                                                                                                                                                                                                                                               |
| Admitted to ICU Derived (CSA Programming Field Only)                                  | _____                                                                                                                                                                                                                                                                           |

US3742169

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:15:04

|                                                                |                                                                                                                                                                  |
|----------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| AEID                                                           |                                                                                                                                                                  |
| Adverse event                                                  | CONSTIPATION                                                                                                                                                     |
| Was this a medically-attended AE?                              | Yes <input type="radio"/><br>No <input checked="" type="radio"/>                                                                                                 |
| Was this a Solicited Adverse Reaction?                         | Yes <input type="radio"/><br>No <input checked="" type="radio"/>                                                                                                 |
| Is this event a confirmed diagnosis of Symptomatic Covid-19?   | Yes <input type="radio"/><br>No <input checked="" type="radio"/>                                                                                                 |
| Start date (dd MMM yyyy)                                       | 22 OCT 2020                                                                                                                                                      |
| Start time (00:00-23:59)                                       |                                                                                                                                                                  |
| AE start date and time (derived)                               |                                                                                                                                                                  |
| Ongoing?                                                       | Yes <input checked="" type="radio"/><br>No <input type="radio"/>                                                                                                 |
| If not Ongoing, end date (dd MMM yyyy)                         |                                                                                                                                                                  |
| End time (00:00-23:59)                                         |                                                                                                                                                                  |
| AE End Date and Time (derived)                                 |                                                                                                                                                                  |
| Severity                                                       | Grade 1/Mild <input type="radio"/><br>Grade 2/Moderate <input checked="" type="radio"/><br>Grade 3/Severe <input type="radio"/><br>Grade 4 <input type="radio"/> |
| Is the adverse event serious?                                  | Yes <input type="radio"/><br>No <input checked="" type="radio"/>                                                                                                 |
| AE is serious due To (check all that apply)                    |                                                                                                                                                                  |
| Death                                                          | False                                                                                                                                                            |
| Life threatening                                               | False                                                                                                                                                            |
| Requires inpatient or prolongation of existing Hospitalization | False                                                                                                                                                            |
| Hospital Admission Date (dd MMM yyyy)                          |                                                                                                                                                                  |
| Hospital Discharge Date (dd MMM yyyy)                          |                                                                                                                                                                  |
| Admitted to ICU?                                               | Yes <input type="radio"/><br>No <input type="radio"/><br>Unknown <input type="radio"/>                                                                           |
| Number of Days in ICU                                          |                                                                                                                                                                  |
| Persistent or significant disability or incapacity             | False                                                                                                                                                            |

v6.020 DTW (1102)

393 of 2382

US3742169

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:15:04

|                                                                                       |                                                                                                                                                                                                                                                                                 |
|---------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Congenital anomaly or birth defect                                                    | False                                                                                                                                                                                                                                                                           |
| Other medically important event                                                       | False                                                                                                                                                                                                                                                                           |
| Relationship to investigational product                                               | Not Related <input checked="" type="radio"/><br>Related <input type="radio"/><br>Not Applicable <input type="radio"/>                                                                                                                                                           |
| Relationship to Study Procedure                                                       | Not Related <input checked="" type="radio"/><br>Related <input type="radio"/><br>Not Applicable <input type="radio"/>                                                                                                                                                           |
| Action taken with investigational product                                             | None <input type="radio"/><br>Dose Delayed <input type="radio"/><br>Investigational Product Withdrawn <input type="radio"/><br>Not Applicable <input checked="" type="radio"/>                                                                                                  |
| Other action taken (check all that apply)                                             |                                                                                                                                                                                                                                                                                 |
| None                                                                                  | True                                                                                                                                                                                                                                                                            |
| Concomitant Medication                                                                | False                                                                                                                                                                                                                                                                           |
| Concomitant Procedure                                                                 | False                                                                                                                                                                                                                                                                           |
| Outcome                                                                               | Fatal <input type="radio"/><br>Not Recovered/Not Resolved <input type="radio"/><br>Recovered/Resolved <input type="radio"/><br>Recovered/Resolved with Sequelae <input type="radio"/><br>Recovering/Resolving <input checked="" type="radio"/><br>Unknown <input type="radio"/> |
| If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:<br>_____ |                                                                                                                                                                                                                                                                                 |
| Narrative<br>_____                                                                    |                                                                                                                                                                                                                                                                                 |
| Serious Adverse Event Derived (CSA Programming Field Only)                            | 0                                                                                                                                                                                                                                                                               |
| Medically Attended AE Derived (CSA Programming Field Only)                            | 0                                                                                                                                                                                                                                                                               |
| Admitted to ICU Derived (CSA Programming Field Only)                                  | _____                                                                                                                                                                                                                                                                           |

US3742169

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:15:04

|                                                                |                                                                                                                                                                  |
|----------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| AEID                                                           |                                                                                                                                                                  |
| Adverse event                                                  | VIRAL ILLNESS UNSPECIFIED                                                                                                                                        |
| Was this a medically-attended AE?                              | Yes <input checked="" type="radio"/><br>No <input type="radio"/>                                                                                                 |
| Was this a Solicited Adverse Reaction?                         | Yes <input type="radio"/><br>No <input checked="" type="radio"/>                                                                                                 |
| Is this event a confirmed diagnosis of Symptomatic Covid-19?   | Yes <input type="radio"/><br>No <input checked="" type="radio"/>                                                                                                 |
| Start date (dd MMM yyyy)                                       | 31 OCT 2020                                                                                                                                                      |
| Start time (00:00-23:59)                                       |                                                                                                                                                                  |
| AE start date and time (derived)                               |                                                                                                                                                                  |
| Ongoing?                                                       | Yes <input type="radio"/><br>No <input checked="" type="radio"/>                                                                                                 |
| If not Ongoing, end date (dd MMM yyyy)                         | 14 NOV 2020                                                                                                                                                      |
| End time (00:00-23:59)                                         |                                                                                                                                                                  |
| AE End Date and Time (derived)                                 |                                                                                                                                                                  |
| Severity                                                       | Grade 1/Mild <input type="radio"/><br>Grade 2/Moderate <input checked="" type="radio"/><br>Grade 3/Severe <input type="radio"/><br>Grade 4 <input type="radio"/> |
| Is the adverse event serious?                                  | Yes <input type="radio"/><br>No <input checked="" type="radio"/>                                                                                                 |
| AE is serious due To (check all that apply)                    |                                                                                                                                                                  |
| Death                                                          | False                                                                                                                                                            |
| Life threatening                                               | False                                                                                                                                                            |
| Requires inpatient or prolongation of existing Hospitalization | False                                                                                                                                                            |
| Hospital Admission Date (dd MMM yyyy)                          |                                                                                                                                                                  |
| Hospital Discharge Date (dd MMM yyyy)                          |                                                                                                                                                                  |
| Admitted to ICU?                                               | Yes <input type="radio"/><br>No <input type="radio"/><br>Unknown <input type="radio"/>                                                                           |
| Number of Days in ICU                                          |                                                                                                                                                                  |
| Persistent or significant disability or incapacity             | False                                                                                                                                                            |
| v6.020 DTW (1102)                                              | 395 of 2382                                                                                                                                                      |

US3742169

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:15:04

|                                                                                       |                                                                                                                                                                                                                                                                                 |
|---------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Congenital anomaly or birth defect                                                    | False                                                                                                                                                                                                                                                                           |
| Other medically important event                                                       | False                                                                                                                                                                                                                                                                           |
| Relationship to investigational product                                               | Not Related <input checked="" type="radio"/><br>Related <input type="radio"/><br>Not Applicable <input type="radio"/>                                                                                                                                                           |
| Relationship to Study Procedure                                                       | Not Related <input checked="" type="radio"/><br>Related <input type="radio"/><br>Not Applicable <input type="radio"/>                                                                                                                                                           |
| Action taken with investigational product                                             | None <input type="radio"/><br>Dose Delayed <input type="radio"/><br>Investigational Product Withdrawn <input type="radio"/><br>Not Applicable <input checked="" type="radio"/>                                                                                                  |
| Other action taken (check all that apply)                                             |                                                                                                                                                                                                                                                                                 |
| None                                                                                  | False                                                                                                                                                                                                                                                                           |
| Concomitant Medication                                                                | True                                                                                                                                                                                                                                                                            |
| Concomitant Procedure                                                                 | False                                                                                                                                                                                                                                                                           |
| Outcome                                                                               | Fatal <input type="radio"/><br>Not Recovered/Not Resolved <input type="radio"/><br>Recovered/Resolved <input checked="" type="radio"/><br>Recovered/Resolved with Sequelae <input type="radio"/><br>Recovering/Resolving <input type="radio"/><br>Unknown <input type="radio"/> |
| If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:<br>_____ |                                                                                                                                                                                                                                                                                 |
| Narrative<br>_____                                                                    |                                                                                                                                                                                                                                                                                 |
| Serious Adverse Event Derived (CSA Programming Field Only)                            | 0                                                                                                                                                                                                                                                                               |
| Medically Attended AE Derived (CSA Programming Field Only)                            | 1                                                                                                                                                                                                                                                                               |
| Admitted to ICU Derived (CSA Programming Field Only)<br>_____                         |                                                                                                                                                                                                                                                                                 |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination Summary**

**Generated On: 26 Nov 2020 11:15:04**

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Were any prior/concomitant medications and/or vaccinations taken?

Yes ☒

No ☐

---

**If Yes, please complete Prior/Concomitant Medication and Vaccination form.**

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US3742169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:15:04

|                                |                                                                                                                                                                                                                                                                                                                                                                                                                          |
|--------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Name of Medication             | RABEPRAZOLE                                                                                                                                                                                                                                                                                                                                                                                                              |
| Prophylaxis                    | Yes <input type="radio"/><br>No <input checked="" type="radio"/>                                                                                                                                                                                                                                                                                                                                                         |
| Indication                     | GASTROESOPHAGEAL REFLUX<br>DISEASE                                                                                                                                                                                                                                                                                                                                                                                       |
| Dose per administration        | 20                                                                                                                                                                                                                                                                                                                                                                                                                       |
| Dose unit                      | mg <input checked="" type="radio"/><br>ug <input type="radio"/><br>mL <input type="radio"/><br>g <input type="radio"/><br>IU <input type="radio"/><br>tablet <input type="radio"/><br>capsule <input type="radio"/><br>puff <input type="radio"/><br>Other <input type="radio"/>                                                                                                                                         |
| If dose unit is Other, specify |                                                                                                                                                                                                                                                                                                                                                                                                                          |
| Frequency                      | once daily <input checked="" type="radio"/><br>twice daily <input type="radio"/><br>three times daily <input type="radio"/><br>four times daily <input type="radio"/><br>every other day <input type="radio"/><br>every week <input type="radio"/><br>every month <input type="radio"/><br>as needed <input type="radio"/><br>once <input type="radio"/><br>unknown <input type="radio"/><br>other <input type="radio"/> |
| If frequency is Other, specify |                                                                                                                                                                                                                                                                                                                                                                                                                          |
| Route of administration        | Oral <input checked="" type="radio"/><br>Topical <input type="radio"/><br>Subcutaneous <input type="radio"/><br>Transdermal <input type="radio"/><br>Intraocular <input type="radio"/>                                                                                                                                                                                                                                   |

US3742169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:15:04

|                                                    |                          |                                  |
|----------------------------------------------------|--------------------------|----------------------------------|
|                                                    | Intramuscular            | <input type="radio"/>            |
|                                                    | Respiratory (Inhalation) | <input type="radio"/>            |
|                                                    | Intralesional            | <input type="radio"/>            |
|                                                    | Intraperitoneal          | <input type="radio"/>            |
|                                                    | Nasal                    | <input type="radio"/>            |
|                                                    | Vaginal                  | <input type="radio"/>            |
|                                                    | Rectal                   | <input type="radio"/>            |
|                                                    | Intravenous              | <input type="radio"/>            |
|                                                    | Intravenous Bolus        | <input type="radio"/>            |
|                                                    | Intravenous Drip         | <input type="radio"/>            |
|                                                    | Other                    | <input type="radio"/>            |
| If route of administration is Other, specify _____ |                          |                                  |
| Start date (dd MMM yyyy)                           | UN                       | UNK 2010                         |
| Start date completely unknown                      |                          | False                            |
| Ongoing?                                           | Yes                      | <input checked="" type="radio"/> |
|                                                    | No                       | <input type="radio"/>            |
| If not Ongoing, End date (dd MMM yyyy) _____       |                          |                                  |
| Was this medication taken for solicited event?     | Yes                      | <input type="radio"/>            |
|                                                    | No                       | <input checked="" type="radio"/> |
| Separate Dosage Number (derived)                   |                          | 1                                |
| Interval Dosage Unit Number (derived)              |                          | 1                                |
| Interval Dosage Definition (derived)               | 802                      | <input type="radio"/>            |
|                                                    | 803                      | <input type="radio"/>            |
|                                                    | 804                      | <input checked="" type="radio"/> |



US3742169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:15:04

|                                |                                                                                                                                                                                                                                                                                                                                                                                                                          |
|--------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Name of Medication             | LEVOTHYROXINE                                                                                                                                                                                                                                                                                                                                                                                                            |
| Prophylaxis                    | Yes <input type="radio"/><br>No <input checked="" type="radio"/>                                                                                                                                                                                                                                                                                                                                                         |
| Indication                     | HYPOTHYROIDISM                                                                                                                                                                                                                                                                                                                                                                                                           |
| Dose per administration        | 100                                                                                                                                                                                                                                                                                                                                                                                                                      |
| Dose unit                      | mg <input type="radio"/><br>ug <input checked="" type="radio"/><br>mL <input type="radio"/><br>g <input type="radio"/><br>IU <input type="radio"/><br>tablet <input type="radio"/><br>capsule <input type="radio"/><br>puff <input type="radio"/><br>Other <input type="radio"/>                                                                                                                                         |
| If dose unit is Other, specify |                                                                                                                                                                                                                                                                                                                                                                                                                          |
| Frequency                      | once daily <input checked="" type="radio"/><br>twice daily <input type="radio"/><br>three times daily <input type="radio"/><br>four times daily <input type="radio"/><br>every other day <input type="radio"/><br>every week <input type="radio"/><br>every month <input type="radio"/><br>as needed <input type="radio"/><br>once <input type="radio"/><br>unknown <input type="radio"/><br>other <input type="radio"/> |
| If frequency is Other, specify |                                                                                                                                                                                                                                                                                                                                                                                                                          |
| Route of administration        | Oral <input checked="" type="radio"/><br>Topical <input type="radio"/><br>Subcutaneous <input type="radio"/><br>Transdermal <input type="radio"/><br>Intraocular <input type="radio"/><br>Intramuscular <input type="radio"/>                                                                                                                                                                                            |

US3742169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:15:04

|                                                                   |                          |                                  |
|-------------------------------------------------------------------|--------------------------|----------------------------------|
|                                                                   | Respiratory (Inhalation) | <input type="checkbox"/>         |
|                                                                   | Intralesional            | <input type="checkbox"/>         |
|                                                                   | Intraperitoneal          | <input type="checkbox"/>         |
|                                                                   | Nasal                    | <input type="checkbox"/>         |
|                                                                   | Vaginal                  | <input type="checkbox"/>         |
|                                                                   | Rectal                   | <input type="checkbox"/>         |
|                                                                   | Intravenous              | <input type="checkbox"/>         |
|                                                                   | Intravenous Bolus        | <input type="checkbox"/>         |
|                                                                   | Intravenous Drip         | <input type="checkbox"/>         |
|                                                                   | Other                    | <input type="checkbox"/>         |
| <hr/>                                                             |                          |                                  |
| If route of administration is Other, specify <input type="text"/> |                          |                                  |
| <hr/>                                                             |                          |                                  |
| Start date (dd MMM yyyy)                                          | UN                       | UNK 1990                         |
| Start date completely unknown                                     | False                    |                                  |
| Ongoing?                                                          | Yes                      | <input checked="" type="radio"/> |
|                                                                   | No                       | <input type="radio"/>            |
| <hr/>                                                             |                          |                                  |
| If not Ongoing, End date (dd MMM yyyy) <input type="text"/>       |                          |                                  |
| <hr/>                                                             |                          |                                  |
| Was this medication taken for solicited event?                    | Yes                      | <input type="radio"/>            |
|                                                                   | No                       | <input checked="" type="radio"/> |
| <hr/>                                                             |                          |                                  |
| Separate Dosage Number (derived)                                  | 1                        |                                  |
| Interval Dosage Unit Number (derived)                             | 1                        |                                  |
| Interval Dosage Definition (derived)                              | 802                      | <input type="radio"/>            |
|                                                                   | 803                      | <input type="radio"/>            |
|                                                                   | 804                      | <input checked="" type="radio"/> |

US3742169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:15:04

|                                |                                                                                                                                                                                                                                                                                                                                                                                                                          |
|--------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Name of Medication             | ENALAPRIL                                                                                                                                                                                                                                                                                                                                                                                                                |
| Prophylaxis                    | Yes <input type="radio"/><br>No <input checked="" type="radio"/>                                                                                                                                                                                                                                                                                                                                                         |
| Indication                     | HYPERTENSION                                                                                                                                                                                                                                                                                                                                                                                                             |
| Dose per administration        | 5                                                                                                                                                                                                                                                                                                                                                                                                                        |
| Dose unit                      | mg <input checked="" type="radio"/><br>ug <input type="radio"/><br>mL <input type="radio"/><br>g <input type="radio"/><br>IU <input type="radio"/><br>tablet <input type="radio"/><br>capsule <input type="radio"/><br>puff <input type="radio"/><br>Other <input type="radio"/>                                                                                                                                         |
| If dose unit is Other, specify |                                                                                                                                                                                                                                                                                                                                                                                                                          |
| Frequency                      | once daily <input checked="" type="radio"/><br>twice daily <input type="radio"/><br>three times daily <input type="radio"/><br>four times daily <input type="radio"/><br>every other day <input type="radio"/><br>every week <input type="radio"/><br>every month <input type="radio"/><br>as needed <input type="radio"/><br>once <input type="radio"/><br>unknown <input type="radio"/><br>other <input type="radio"/> |
| If frequency is Other, specify |                                                                                                                                                                                                                                                                                                                                                                                                                          |
| Route of administration        | Oral <input checked="" type="radio"/><br>Topical <input type="radio"/><br>Subcutaneous <input type="radio"/><br>Transdermal <input type="radio"/><br>Intraocular <input type="radio"/><br>Intramuscular <input type="radio"/>                                                                                                                                                                                            |

US3742169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:15:04

|                                                                   |                          |                                  |
|-------------------------------------------------------------------|--------------------------|----------------------------------|
|                                                                   | Respiratory (Inhalation) | <input type="checkbox"/>         |
|                                                                   | Intralesional            | <input type="checkbox"/>         |
|                                                                   | Intraperitoneal          | <input type="checkbox"/>         |
|                                                                   | Nasal                    | <input type="checkbox"/>         |
|                                                                   | Vaginal                  | <input type="checkbox"/>         |
|                                                                   | Rectal                   | <input type="checkbox"/>         |
|                                                                   | Intravenous              | <input type="checkbox"/>         |
|                                                                   | Intravenous Bolus        | <input type="checkbox"/>         |
|                                                                   | Intravenous Drip         | <input type="checkbox"/>         |
|                                                                   | Other                    | <input type="checkbox"/>         |
| <hr/>                                                             |                          |                                  |
| If route of administration is Other, specify <input type="text"/> |                          |                                  |
| <hr/>                                                             |                          |                                  |
| Start date (dd MMM yyyy)                                          | UN                       | UNK 2018                         |
| Start date completely unknown                                     | False                    |                                  |
| Ongoing?                                                          | Yes                      | <input checked="" type="radio"/> |
|                                                                   | No                       | <input type="radio"/>            |
| <hr/>                                                             |                          |                                  |
| If not Ongoing, End date (dd MMM yyyy) <input type="text"/>       |                          |                                  |
| <hr/>                                                             |                          |                                  |
| Was this medication taken for solicited event?                    | Yes                      | <input type="radio"/>            |
|                                                                   | No                       | <input checked="" type="radio"/> |
| <hr/>                                                             |                          |                                  |
| Separate Dosage Number (derived)                                  | 1                        |                                  |
| Interval Dosage Unit Number (derived)                             | 1                        |                                  |
| Interval Dosage Definition (derived)                              | 802                      | <input type="radio"/>            |
|                                                                   | 803                      | <input type="radio"/>            |
|                                                                   | 804                      | <input checked="" type="radio"/> |

US3742169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

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|                                |                                                                                                                                                                                                                                                                                                                                                                                                                          |
|--------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Name of Medication             | BREO ELLIPTA                                                                                                                                                                                                                                                                                                                                                                                                             |
| Prophylaxis                    | Yes <input type="radio"/><br>No <input checked="" type="radio"/>                                                                                                                                                                                                                                                                                                                                                         |
| Indication                     | ASTHMA                                                                                                                                                                                                                                                                                                                                                                                                                   |
| Dose per administration        | 100/25                                                                                                                                                                                                                                                                                                                                                                                                                   |
| Dose unit                      | mg <input type="radio"/><br>ug <input checked="" type="radio"/><br>mL <input type="radio"/><br>g <input type="radio"/><br>IU <input type="radio"/><br>tablet <input type="radio"/><br>capsule <input type="radio"/><br>puff <input type="radio"/><br>Other <input type="radio"/>                                                                                                                                         |
| If dose unit is Other, specify |                                                                                                                                                                                                                                                                                                                                                                                                                          |
| Frequency                      | once daily <input type="radio"/><br>twice daily <input type="radio"/><br>three times daily <input type="radio"/><br>four times daily <input type="radio"/><br>every other day <input type="radio"/><br>every week <input type="radio"/><br>every month <input type="radio"/><br>as needed <input checked="" type="radio"/><br>once <input type="radio"/><br>unknown <input type="radio"/><br>other <input type="radio"/> |
| If frequency is Other, specify |                                                                                                                                                                                                                                                                                                                                                                                                                          |
| Route of administration        | Oral <input type="radio"/><br>Topical <input type="radio"/><br>Subcutaneous <input type="radio"/><br>Transdermal <input type="radio"/><br>Intraocular <input type="radio"/><br>Intramuscular <input type="radio"/>                                                                                                                                                                                                       |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:15:04

|                                                    |                          |                                  |
|----------------------------------------------------|--------------------------|----------------------------------|
|                                                    | Respiratory (Inhalation) | <input checked="" type="radio"/> |
|                                                    | Intralesional            | <input type="radio"/>            |
|                                                    | Intraperitoneal          | <input type="radio"/>            |
|                                                    | Nasal                    | <input type="radio"/>            |
|                                                    | Vaginal                  | <input type="radio"/>            |
|                                                    | Rectal                   | <input type="radio"/>            |
|                                                    | Intravenous              | <input type="radio"/>            |
|                                                    | Intravenous Bolus        | <input type="radio"/>            |
|                                                    | Intravenous Drip         | <input type="radio"/>            |
|                                                    | Other                    | <input type="radio"/>            |
| <hr/>                                              |                          |                                  |
| If route of administration is Other, specify <hr/> |                          |                                  |
| Start date (dd MMM yyyy)                           | UN AUG 2020              |                                  |
| Start date completely unknown                      | False                    |                                  |
| Ongoing?                                           | Yes                      | <input checked="" type="radio"/> |
|                                                    | No                       | <input type="radio"/>            |
| <hr/>                                              |                          |                                  |
| If not Ongoing, End date (dd MMM yyyy) <hr/>       |                          |                                  |
| Was this medication taken for solicited event?     | Yes                      | <input type="radio"/>            |
|                                                    | No                       | <input checked="" type="radio"/> |
| <hr/>                                              |                          |                                  |
| Separate Dosage Number (derived)                   | <hr/>                    |                                  |
| Interval Dosage Unit Number (derived)              | <hr/>                    |                                  |
| Interval Dosage Definition (derived)               | 802                      | <input type="radio"/>            |
|                                                    | 803                      | <input type="radio"/>            |
|                                                    | 804                      | <input type="radio"/>            |

US3742169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

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|                                |                                                                                                                                                                                                                                                                                                                                                                                                                          |
|--------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Name of Medication             | ALBUTEROL                                                                                                                                                                                                                                                                                                                                                                                                                |
| Prophylaxis                    | Yes <input type="radio"/><br>No <input checked="" type="radio"/>                                                                                                                                                                                                                                                                                                                                                         |
| Indication                     | ASTHMA                                                                                                                                                                                                                                                                                                                                                                                                                   |
| Dose per administration        | 90                                                                                                                                                                                                                                                                                                                                                                                                                       |
| Dose unit                      | mg <input type="radio"/><br>ug <input checked="" type="radio"/><br>mL <input type="radio"/><br>g <input type="radio"/><br>IU <input type="radio"/><br>tablet <input type="radio"/><br>capsule <input type="radio"/><br>puff <input type="radio"/><br>Other <input type="radio"/>                                                                                                                                         |
| If dose unit is Other, specify |                                                                                                                                                                                                                                                                                                                                                                                                                          |
| Frequency                      | once daily <input type="radio"/><br>twice daily <input type="radio"/><br>three times daily <input type="radio"/><br>four times daily <input type="radio"/><br>every other day <input type="radio"/><br>every week <input type="radio"/><br>every month <input type="radio"/><br>as needed <input checked="" type="radio"/><br>once <input type="radio"/><br>unknown <input type="radio"/><br>other <input type="radio"/> |
| If frequency is Other, specify |                                                                                                                                                                                                                                                                                                                                                                                                                          |
| Route of administration        | Oral <input type="radio"/><br>Topical <input type="radio"/><br>Subcutaneous <input type="radio"/><br>Transdermal <input type="radio"/><br>Intraocular <input type="radio"/><br>Intramuscular <input type="radio"/>                                                                                                                                                                                                       |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:15:04

|                                                    |                          |                                  |
|----------------------------------------------------|--------------------------|----------------------------------|
|                                                    | Respiratory (Inhalation) | <input checked="" type="radio"/> |
|                                                    | Intralesional            | <input type="radio"/>            |
|                                                    | Intraperitoneal          | <input type="radio"/>            |
|                                                    | Nasal                    | <input type="radio"/>            |
|                                                    | Vaginal                  | <input type="radio"/>            |
|                                                    | Rectal                   | <input type="radio"/>            |
|                                                    | Intravenous              | <input type="radio"/>            |
|                                                    | Intravenous Bolus        | <input type="radio"/>            |
|                                                    | Intravenous Drip         | <input type="radio"/>            |
|                                                    | Other                    | <input type="radio"/>            |
| <hr/>                                              |                          |                                  |
| If route of administration is Other, specify <hr/> |                          |                                  |
| Start date (dd MMM yyyy)                           | UN                       | UNK 2000                         |
| Start date completely unknown                      | False                    |                                  |
| Ongoing?                                           | Yes                      | <input checked="" type="radio"/> |
|                                                    | No                       | <input type="radio"/>            |
| <hr/>                                              |                          |                                  |
| If not Ongoing, End date (dd MMM yyyy) <hr/>       |                          |                                  |
| Was this medication taken for solicited event?     | Yes                      | <input type="radio"/>            |
|                                                    | No                       | <input checked="" type="radio"/> |
| <hr/>                                              |                          |                                  |
| Separate Dosage Number (derived)                   | <hr/>                    |                                  |
| Interval Dosage Unit Number (derived)              | <hr/>                    |                                  |
| Interval Dosage Definition (derived)               | 802                      | <input type="radio"/>            |
|                                                    | 803                      | <input type="radio"/>            |
|                                                    | 804                      | <input type="radio"/>            |



US3742169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:15:04

|                                |                                                                                                                                                                                                                                                                                                                                                                                                                          |
|--------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Name of Medication             | LEVOCETIRIZINE                                                                                                                                                                                                                                                                                                                                                                                                           |
| Prophylaxis                    | Yes <input type="radio"/><br>No <input checked="" type="radio"/>                                                                                                                                                                                                                                                                                                                                                         |
| Indication                     | ENVIRONMENTAL ALLERGIES                                                                                                                                                                                                                                                                                                                                                                                                  |
| Dose per administration        | 5                                                                                                                                                                                                                                                                                                                                                                                                                        |
| Dose unit                      | mg <input checked="" type="radio"/><br>ug <input type="radio"/><br>mL <input type="radio"/><br>g <input type="radio"/><br>IU <input type="radio"/><br>tablet <input type="radio"/><br>capsule <input type="radio"/><br>puff <input type="radio"/><br>Other <input type="radio"/>                                                                                                                                         |
| If dose unit is Other, specify |                                                                                                                                                                                                                                                                                                                                                                                                                          |
| Frequency                      | once daily <input checked="" type="radio"/><br>twice daily <input type="radio"/><br>three times daily <input type="radio"/><br>four times daily <input type="radio"/><br>every other day <input type="radio"/><br>every week <input type="radio"/><br>every month <input type="radio"/><br>as needed <input type="radio"/><br>once <input type="radio"/><br>unknown <input type="radio"/><br>other <input type="radio"/> |
| If frequency is Other, specify |                                                                                                                                                                                                                                                                                                                                                                                                                          |
| Route of administration        | Oral <input checked="" type="radio"/><br>Topical <input type="radio"/><br>Subcutaneous <input type="radio"/><br>Transdermal <input type="radio"/><br>Intraocular <input type="radio"/><br>Intramuscular <input type="radio"/>                                                                                                                                                                                            |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:15:04

|                                                                   |                          |                                  |
|-------------------------------------------------------------------|--------------------------|----------------------------------|
|                                                                   | Respiratory (Inhalation) | <input type="checkbox"/>         |
|                                                                   | Intralesional            | <input type="checkbox"/>         |
|                                                                   | Intraperitoneal          | <input type="checkbox"/>         |
|                                                                   | Nasal                    | <input type="checkbox"/>         |
|                                                                   | Vaginal                  | <input type="checkbox"/>         |
|                                                                   | Rectal                   | <input type="checkbox"/>         |
|                                                                   | Intravenous              | <input type="checkbox"/>         |
|                                                                   | Intravenous Bolus        | <input type="checkbox"/>         |
|                                                                   | Intravenous Drip         | <input type="checkbox"/>         |
|                                                                   | Other                    | <input type="checkbox"/>         |
| <hr/>                                                             |                          |                                  |
| If route of administration is Other, specify <input type="text"/> |                          |                                  |
| <hr/>                                                             |                          |                                  |
| Start date (dd MMM yyyy)                                          | UN                       | UNK 2018                         |
| Start date completely unknown                                     | False                    |                                  |
| Ongoing?                                                          | Yes                      | <input checked="" type="radio"/> |
|                                                                   | No                       | <input type="radio"/>            |
| <hr/>                                                             |                          |                                  |
| If not Ongoing, End date (dd MMM yyyy) <input type="text"/>       |                          |                                  |
| <hr/>                                                             |                          |                                  |
| Was this medication taken for solicited event?                    | Yes                      | <input type="radio"/>            |
|                                                                   | No                       | <input checked="" type="radio"/> |
| <hr/>                                                             |                          |                                  |
| Separate Dosage Number (derived)                                  | 1                        |                                  |
| Interval Dosage Unit Number (derived)                             | 1                        |                                  |
| Interval Dosage Definition (derived)                              | 802                      | <input type="radio"/>            |
|                                                                   | 803                      | <input type="radio"/>            |
|                                                                   | 804                      | <input checked="" type="radio"/> |

US3742169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

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|                                |                                                                                                                                                                                                                                                                                                                                                                                                                          |
|--------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Name of Medication             | MONTELUKAST                                                                                                                                                                                                                                                                                                                                                                                                              |
| Prophylaxis                    | Yes <input type="radio"/><br>No <input checked="" type="radio"/>                                                                                                                                                                                                                                                                                                                                                         |
| Indication                     | ENVIRONMENTAL ALLERGIES                                                                                                                                                                                                                                                                                                                                                                                                  |
| Dose per administration        | 10                                                                                                                                                                                                                                                                                                                                                                                                                       |
| Dose unit                      | mg <input checked="" type="radio"/><br>ug <input type="radio"/><br>mL <input type="radio"/><br>g <input type="radio"/><br>IU <input type="radio"/><br>tablet <input type="radio"/><br>capsule <input type="radio"/><br>puff <input type="radio"/><br>Other <input type="radio"/>                                                                                                                                         |
| If dose unit is Other, specify |                                                                                                                                                                                                                                                                                                                                                                                                                          |
| Frequency                      | once daily <input checked="" type="radio"/><br>twice daily <input type="radio"/><br>three times daily <input type="radio"/><br>four times daily <input type="radio"/><br>every other day <input type="radio"/><br>every week <input type="radio"/><br>every month <input type="radio"/><br>as needed <input type="radio"/><br>once <input type="radio"/><br>unknown <input type="radio"/><br>other <input type="radio"/> |
| If frequency is Other, specify |                                                                                                                                                                                                                                                                                                                                                                                                                          |
| Route of administration        | Oral <input checked="" type="radio"/><br>Topical <input type="radio"/><br>Subcutaneous <input type="radio"/><br>Transdermal <input type="radio"/><br>Intraocular <input type="radio"/><br>Intramuscular <input type="radio"/>                                                                                                                                                                                            |

US3742169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:15:04

|                                                                   |                          |                                  |
|-------------------------------------------------------------------|--------------------------|----------------------------------|
|                                                                   | Respiratory (Inhalation) | <input type="checkbox"/>         |
|                                                                   | Intralesional            | <input type="checkbox"/>         |
|                                                                   | Intraperitoneal          | <input type="checkbox"/>         |
|                                                                   | Nasal                    | <input type="checkbox"/>         |
|                                                                   | Vaginal                  | <input type="checkbox"/>         |
|                                                                   | Rectal                   | <input type="checkbox"/>         |
|                                                                   | Intravenous              | <input type="checkbox"/>         |
|                                                                   | Intravenous Bolus        | <input type="checkbox"/>         |
|                                                                   | Intravenous Drip         | <input type="checkbox"/>         |
|                                                                   | Other                    | <input type="checkbox"/>         |
| <hr/>                                                             |                          |                                  |
| If route of administration is Other, specify <input type="text"/> |                          |                                  |
| <hr/>                                                             |                          |                                  |
| Start date (dd MMM yyyy)                                          | UN                       | UNK 1990                         |
| Start date completely unknown                                     | False                    |                                  |
| Ongoing?                                                          | Yes                      | <input checked="" type="radio"/> |
|                                                                   | No                       | <input type="radio"/>            |
| <hr/>                                                             |                          |                                  |
| If not Ongoing, End date (dd MMM yyyy) <input type="text"/>       |                          |                                  |
| <hr/>                                                             |                          |                                  |
| Was this medication taken for solicited event?                    | Yes                      | <input type="radio"/>            |
|                                                                   | No                       | <input checked="" type="radio"/> |
| <hr/>                                                             |                          |                                  |
| Separate Dosage Number (derived)                                  | 1                        |                                  |
| Interval Dosage Unit Number (derived)                             | 1                        |                                  |
| Interval Dosage Definition (derived)                              | 802                      | <input type="radio"/>            |
|                                                                   | 803                      | <input type="radio"/>            |
|                                                                   | 804                      | <input checked="" type="radio"/> |

US3742169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

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|                                |                                                                                                                                                                                                                                                                                                                                                                                                                          |
|--------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Name of Medication             | FIBER GUMMIES                                                                                                                                                                                                                                                                                                                                                                                                            |
| Prophylaxis                    | Yes <input type="radio"/><br>No <input checked="" type="radio"/>                                                                                                                                                                                                                                                                                                                                                         |
| Indication                     | CONSTIPATION                                                                                                                                                                                                                                                                                                                                                                                                             |
| Dose per administration        | 2                                                                                                                                                                                                                                                                                                                                                                                                                        |
| Dose unit                      | mg <input type="radio"/><br>ug <input type="radio"/><br>mL <input type="radio"/><br>g <input type="radio"/><br>IU <input type="radio"/><br>tablet <input type="radio"/><br>capsule <input type="radio"/><br>puff <input type="radio"/><br>Other <input checked="" type="radio"/>                                                                                                                                         |
| If dose unit is Other, specify | GUMMIES                                                                                                                                                                                                                                                                                                                                                                                                                  |
| Frequency                      | once daily <input checked="" type="radio"/><br>twice daily <input type="radio"/><br>three times daily <input type="radio"/><br>four times daily <input type="radio"/><br>every other day <input type="radio"/><br>every week <input type="radio"/><br>every month <input type="radio"/><br>as needed <input type="radio"/><br>once <input type="radio"/><br>unknown <input type="radio"/><br>other <input type="radio"/> |
| If frequency is Other, specify |                                                                                                                                                                                                                                                                                                                                                                                                                          |
| Route of administration        | Oral <input checked="" type="radio"/><br>Topical <input type="radio"/><br>Subcutaneous <input type="radio"/><br>Transdermal <input type="radio"/><br>Intraocular <input type="radio"/><br>Intramuscular <input type="radio"/>                                                                                                                                                                                            |

US3742169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:15:04

|                                                                   |                          |                                  |
|-------------------------------------------------------------------|--------------------------|----------------------------------|
|                                                                   | Respiratory (Inhalation) | <input type="checkbox"/>         |
|                                                                   | Intralesional            | <input type="checkbox"/>         |
|                                                                   | Intraperitoneal          | <input type="checkbox"/>         |
|                                                                   | Nasal                    | <input type="checkbox"/>         |
|                                                                   | Vaginal                  | <input type="checkbox"/>         |
|                                                                   | Rectal                   | <input type="checkbox"/>         |
|                                                                   | Intravenous              | <input type="checkbox"/>         |
|                                                                   | Intravenous Bolus        | <input type="checkbox"/>         |
|                                                                   | Intravenous Drip         | <input type="checkbox"/>         |
|                                                                   | Other                    | <input type="checkbox"/>         |
| <hr/>                                                             |                          |                                  |
| If route of administration is Other, specify <input type="text"/> |                          |                                  |
| <hr/>                                                             |                          |                                  |
| Start date (dd MMM yyyy)                                          |                          | 15 SEP 2020                      |
| Start date completely unknown                                     |                          | False                            |
| Ongoing?                                                          | Yes                      | <input checked="" type="radio"/> |
|                                                                   | No                       | <input type="radio"/>            |
| <hr/>                                                             |                          |                                  |
| If not Ongoing, End date (dd MMM yyyy) <input type="text"/>       |                          |                                  |
| <hr/>                                                             |                          |                                  |
| Was this medication taken for solicited event?                    | Yes                      | <input type="radio"/>            |
|                                                                   | No                       | <input checked="" type="radio"/> |
| <hr/>                                                             |                          |                                  |
| Separate Dosage Number (derived)                                  |                          | 1                                |
| Interval Dosage Unit Number (derived)                             |                          | 1                                |
| Interval Dosage Definition (derived)                              | 802                      | <input type="radio"/>            |
|                                                                   | 803                      | <input type="radio"/>            |
|                                                                   | 804                      | <input checked="" type="radio"/> |

US3742169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

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Name of Medication PHENYLEPHRINE/ COCOA  
BUTTER 0.25/88%  
SUPPOSITORIES

Prophylaxis Yes ☐  
No ☒

Indication CONSTIPATION

Dose per administration 1

Dose unit mg ☐  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☒

If dose unit is Other, specify APPLICATION

Frequency once daily ☐  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☒  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

US3742169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:15:04

|                                                    |                          |                                  |
|----------------------------------------------------|--------------------------|----------------------------------|
|                                                    | Intraocular              | <input type="radio"/>            |
|                                                    | Intramuscular            | <input type="radio"/>            |
|                                                    | Respiratory (Inhalation) | <input type="radio"/>            |
|                                                    | Intralesional            | <input type="radio"/>            |
|                                                    | Intraperitoneal          | <input type="radio"/>            |
|                                                    | Nasal                    | <input type="radio"/>            |
|                                                    | Vaginal                  | <input type="radio"/>            |
|                                                    | Rectal                   | <input checked="" type="radio"/> |
|                                                    | Intravenous              | <input type="radio"/>            |
|                                                    | Intravenous Bolus        | <input type="radio"/>            |
|                                                    | Intravenous Drip         | <input type="radio"/>            |
|                                                    | Other                    | <input type="radio"/>            |
| If route of administration is Other, specify _____ |                          |                                  |
| Start date (dd MMM yyyy)                           | 16 SEP 2020              |                                  |
| Start date completely unknown                      | False                    |                                  |
| Ongoing?                                           | Yes                      | <input type="radio"/>            |
|                                                    | No                       | <input checked="" type="radio"/> |
| If not Ongoing, End date (dd MMM yyyy)             |                          | 16 SEP 2020                      |
| Was this medication taken for solicited event?     | Yes                      | <input type="radio"/>            |
|                                                    | No                       | <input checked="" type="radio"/> |
| Separate Dosage Number (derived) _____             |                          |                                  |
| Interval Dosage Unit Number (derived) _____        |                          |                                  |
| Interval Dosage Definition (derived)               | 802                      | <input type="radio"/>            |
|                                                    | 803                      | <input type="radio"/>            |
|                                                    | 804                      | <input type="radio"/>            |



US3742169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:15:04

|                                |                                                                                                                                                                                                                                                                                                                                                                                                                          |
|--------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Name of Medication             | TYLENOL GEL CAPS                                                                                                                                                                                                                                                                                                                                                                                                         |
| Prophylaxis                    | Yes <input type="radio"/><br>No <input checked="" type="radio"/>                                                                                                                                                                                                                                                                                                                                                         |
| Indication                     | RHEUMATOID ARTHRITIS                                                                                                                                                                                                                                                                                                                                                                                                     |
| Dose per administration        | 650                                                                                                                                                                                                                                                                                                                                                                                                                      |
| Dose unit                      | mg <input checked="" type="radio"/><br>ug <input type="radio"/><br>mL <input type="radio"/><br>g <input type="radio"/><br>IU <input type="radio"/><br>tablet <input type="radio"/><br>capsule <input type="radio"/><br>puff <input type="radio"/><br>Other <input type="radio"/>                                                                                                                                         |
| If dose unit is Other, specify |                                                                                                                                                                                                                                                                                                                                                                                                                          |
| Frequency                      | once daily <input type="radio"/><br>twice daily <input type="radio"/><br>three times daily <input type="radio"/><br>four times daily <input type="radio"/><br>every other day <input type="radio"/><br>every week <input type="radio"/><br>every month <input type="radio"/><br>as needed <input checked="" type="radio"/><br>once <input type="radio"/><br>unknown <input type="radio"/><br>other <input type="radio"/> |
| If frequency is Other, specify |                                                                                                                                                                                                                                                                                                                                                                                                                          |
| Route of administration        | Oral <input checked="" type="radio"/><br>Topical <input type="radio"/><br>Subcutaneous <input type="radio"/><br>Transdermal <input type="radio"/><br>Intraocular <input type="radio"/><br>Intramuscular <input type="radio"/>                                                                                                                                                                                            |

US3742169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:15:04

|                                                                   |                          |                                     |
|-------------------------------------------------------------------|--------------------------|-------------------------------------|
|                                                                   | Respiratory (Inhalation) | <input type="checkbox"/>            |
|                                                                   | Intralesional            | <input type="checkbox"/>            |
|                                                                   | Intraperitoneal          | <input type="checkbox"/>            |
|                                                                   | Nasal                    | <input type="checkbox"/>            |
|                                                                   | Vaginal                  | <input type="checkbox"/>            |
|                                                                   | Rectal                   | <input type="checkbox"/>            |
|                                                                   | Intravenous              | <input type="checkbox"/>            |
|                                                                   | Intravenous Bolus        | <input type="checkbox"/>            |
|                                                                   | Intravenous Drip         | <input type="checkbox"/>            |
|                                                                   | Other                    | <input type="checkbox"/>            |
| <hr/>                                                             |                          |                                     |
| If route of administration is Other, specify <input type="text"/> |                          |                                     |
| <hr/>                                                             |                          |                                     |
| Start date (dd MMM yyyy)                                          |                          | 16 SEP 2020                         |
| Start date completely unknown                                     |                          | False                               |
| Ongoing?                                                          | Yes                      | <input type="checkbox"/>            |
|                                                                   | No                       | <input checked="" type="checkbox"/> |
| <hr/>                                                             |                          |                                     |
| If not Ongoing, End date (dd MMM yyyy)                            |                          | 24 SEP 2020                         |
| <hr/>                                                             |                          |                                     |
| Was this medication taken for solicited event?                    | Yes                      | <input type="checkbox"/>            |
|                                                                   | No                       | <input checked="" type="checkbox"/> |
| <hr/>                                                             |                          |                                     |
| Separate Dosage Number (derived)                                  |                          | <input type="text"/>                |
| <hr/>                                                             |                          |                                     |
| Interval Dosage Unit Number (derived)                             |                          | <input type="text"/>                |
| <hr/>                                                             |                          |                                     |
| Interval Dosage Definition (derived)                              | 802                      | <input type="checkbox"/>            |
|                                                                   | 803                      | <input type="checkbox"/>            |
|                                                                   | 804                      | <input type="checkbox"/>            |

US3742169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:15:04

|                                |                                                                                                                                                                                                                                                                                                                                                                                                                          |
|--------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Name of Medication             | TRUNATURE DIGESTIBE<br>PROBIOTIC                                                                                                                                                                                                                                                                                                                                                                                         |
| Prophylaxis                    | Yes <input type="radio"/><br>No <input checked="" type="radio"/>                                                                                                                                                                                                                                                                                                                                                         |
| Indication                     | CONSTIPATION                                                                                                                                                                                                                                                                                                                                                                                                             |
| Dose per administration        | 2                                                                                                                                                                                                                                                                                                                                                                                                                        |
| Dose unit                      | mg <input type="radio"/><br>ug <input type="radio"/><br>mL <input type="radio"/><br>g <input type="radio"/><br>IU <input type="radio"/><br>tablet <input type="radio"/><br>capsule <input type="radio"/><br>puff <input type="radio"/><br>Other <input checked="" type="radio"/>                                                                                                                                         |
| If dose unit is Other, specify | GUMMIES                                                                                                                                                                                                                                                                                                                                                                                                                  |
| Frequency                      | once daily <input type="radio"/><br>twice daily <input type="radio"/><br>three times daily <input type="radio"/><br>four times daily <input type="radio"/><br>every other day <input type="radio"/><br>every week <input type="radio"/><br>every month <input type="radio"/><br>as needed <input checked="" type="radio"/><br>once <input type="radio"/><br>unknown <input type="radio"/><br>other <input type="radio"/> |
| If frequency is Other, specify |                                                                                                                                                                                                                                                                                                                                                                                                                          |
| Route of administration        | Oral <input checked="" type="radio"/><br>Topical <input type="radio"/><br>Subcutaneous <input type="radio"/><br>Transdermal <input type="radio"/><br>Intraocular <input type="radio"/>                                                                                                                                                                                                                                   |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:15:04

|                                                    |                          |                                  |
|----------------------------------------------------|--------------------------|----------------------------------|
|                                                    | Intramuscular            | <input type="checkbox"/>         |
|                                                    | Respiratory (Inhalation) | <input type="checkbox"/>         |
|                                                    | Intralesional            | <input type="checkbox"/>         |
|                                                    | Intraperitoneal          | <input type="checkbox"/>         |
|                                                    | Nasal                    | <input type="checkbox"/>         |
|                                                    | Vaginal                  | <input type="checkbox"/>         |
|                                                    | Rectal                   | <input type="checkbox"/>         |
|                                                    | Intravenous              | <input type="checkbox"/>         |
|                                                    | Intravenous Bolus        | <input type="checkbox"/>         |
|                                                    | Intravenous Drip         | <input type="checkbox"/>         |
|                                                    | Other                    | <input type="checkbox"/>         |
| <hr/>                                              |                          |                                  |
| If route of administration is Other, specify _____ |                          |                                  |
| Start date (dd MMM yyyy)                           |                          | 23 SEP 2020                      |
| Start date completely unknown                      |                          | False                            |
| Ongoing?                                           | Yes                      | <input checked="" type="radio"/> |
|                                                    | No                       | <input type="radio"/>            |
| <hr/>                                              |                          |                                  |
| If not Ongoing, End date (dd MMM yyyy) _____       |                          |                                  |
| Was this medication taken for solicited event?     | Yes                      | <input type="radio"/>            |
|                                                    | No                       | <input checked="" type="radio"/> |
| <hr/>                                              |                          |                                  |
| Separate Dosage Number (derived)                   |                          | _____                            |
| Interval Dosage Unit Number (derived)              |                          | _____                            |
| Interval Dosage Definition (derived)               | 802                      | <input type="radio"/>            |
|                                                    | 803                      | <input type="radio"/>            |
|                                                    | 804                      | <input type="radio"/>            |

US3742169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:15:04

|                                      |                                                                                                                                                                                                                                                                                                                                                                                                                          |
|--------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Name of Medication                   | TYLENOL                                                                                                                                                                                                                                                                                                                                                                                                                  |
| Prophylaxis                          | Yes <input type="radio"/><br>No <input checked="" type="radio"/>                                                                                                                                                                                                                                                                                                                                                         |
| Indication                           | RHEUMATOID ARTHRITIS                                                                                                                                                                                                                                                                                                                                                                                                     |
| Dose per administration              | 1000                                                                                                                                                                                                                                                                                                                                                                                                                     |
| Dose unit                            | mg <input checked="" type="radio"/><br>ug <input type="radio"/><br>mL <input type="radio"/><br>g <input type="radio"/><br>IU <input type="radio"/><br>tablet <input type="radio"/><br>capsule <input type="radio"/><br>puff <input type="radio"/><br>Other <input type="radio"/>                                                                                                                                         |
| If dose unit is Other, specify _____ |                                                                                                                                                                                                                                                                                                                                                                                                                          |
| Frequency                            | once daily <input type="radio"/><br>twice daily <input type="radio"/><br>three times daily <input type="radio"/><br>four times daily <input type="radio"/><br>every other day <input type="radio"/><br>every week <input type="radio"/><br>every month <input type="radio"/><br>as needed <input checked="" type="radio"/><br>once <input type="radio"/><br>unknown <input type="radio"/><br>other <input type="radio"/> |
| If frequency is Other, specify _____ |                                                                                                                                                                                                                                                                                                                                                                                                                          |
| Route of administration              | Oral <input checked="" type="radio"/><br>Topical <input type="radio"/><br>Subcutaneous <input type="radio"/><br>Transdermal <input type="radio"/><br>Intraocular <input type="radio"/><br>Intramuscular <input type="radio"/>                                                                                                                                                                                            |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:15:04

|                                                                   |                          |                                  |
|-------------------------------------------------------------------|--------------------------|----------------------------------|
|                                                                   | Respiratory (Inhalation) | <input type="checkbox"/>         |
|                                                                   | Intralesional            | <input type="checkbox"/>         |
|                                                                   | Intraperitoneal          | <input type="checkbox"/>         |
|                                                                   | Nasal                    | <input type="checkbox"/>         |
|                                                                   | Vaginal                  | <input type="checkbox"/>         |
|                                                                   | Rectal                   | <input type="checkbox"/>         |
|                                                                   | Intravenous              | <input type="checkbox"/>         |
|                                                                   | Intravenous Bolus        | <input type="checkbox"/>         |
|                                                                   | Intravenous Drip         | <input type="checkbox"/>         |
|                                                                   | Other                    | <input type="checkbox"/>         |
| <hr/>                                                             |                          |                                  |
| If route of administration is Other, specify <input type="text"/> |                          |                                  |
| <hr/>                                                             |                          |                                  |
| Start date (dd MMM yyyy)                                          |                          | 9 OCT 2020                       |
| Start date completely unknown                                     |                          | False                            |
| Ongoing?                                                          | Yes                      | <input checked="" type="radio"/> |
|                                                                   | No                       | <input type="radio"/>            |
| <hr/>                                                             |                          |                                  |
| If not Ongoing, End date (dd MMM yyyy) <input type="text"/>       |                          |                                  |
| <hr/>                                                             |                          |                                  |
| Was this medication taken for solicited event?                    | Yes                      | <input type="radio"/>            |
|                                                                   | No                       | <input checked="" type="radio"/> |
| <hr/>                                                             |                          |                                  |
| Separate Dosage Number (derived)                                  |                          | <input type="text"/>             |
| Interval Dosage Unit Number (derived)                             |                          | <input type="text"/>             |
| Interval Dosage Definition (derived)                              | 802                      | <input type="radio"/>            |
|                                                                   | 803                      | <input type="radio"/>            |
|                                                                   | 804                      | <input type="radio"/>            |

US3742169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:15:04

|                                |                                                                                                                                                                                                                                                                                                                                                                                                                          |
|--------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Name of Medication             | MOBIC                                                                                                                                                                                                                                                                                                                                                                                                                    |
| Prophylaxis                    | Yes <input type="radio"/><br>No <input checked="" type="radio"/>                                                                                                                                                                                                                                                                                                                                                         |
| Indication                     | RHEUMATOID ARTHRITIS                                                                                                                                                                                                                                                                                                                                                                                                     |
| Dose per administration        | 7.5                                                                                                                                                                                                                                                                                                                                                                                                                      |
| Dose unit                      | mg <input checked="" type="radio"/><br>ug <input type="radio"/><br>mL <input type="radio"/><br>g <input type="radio"/><br>IU <input type="radio"/><br>tablet <input type="radio"/><br>capsule <input type="radio"/><br>puff <input type="radio"/><br>Other <input type="radio"/>                                                                                                                                         |
| If dose unit is Other, specify |                                                                                                                                                                                                                                                                                                                                                                                                                          |
| Frequency                      | once daily <input type="radio"/><br>twice daily <input type="radio"/><br>three times daily <input type="radio"/><br>four times daily <input type="radio"/><br>every other day <input type="radio"/><br>every week <input type="radio"/><br>every month <input type="radio"/><br>as needed <input checked="" type="radio"/><br>once <input type="radio"/><br>unknown <input type="radio"/><br>other <input type="radio"/> |
| If frequency is Other, specify |                                                                                                                                                                                                                                                                                                                                                                                                                          |
| Route of administration        | Oral <input checked="" type="radio"/><br>Topical <input type="radio"/><br>Subcutaneous <input type="radio"/><br>Transdermal <input type="radio"/><br>Intraocular <input type="radio"/><br>Intramuscular <input type="radio"/>                                                                                                                                                                                            |

US3742169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:15:04

|                                                                   |                          |                                  |
|-------------------------------------------------------------------|--------------------------|----------------------------------|
|                                                                   | Respiratory (Inhalation) | <input type="checkbox"/>         |
|                                                                   | Intralesional            | <input type="checkbox"/>         |
|                                                                   | Intraperitoneal          | <input type="checkbox"/>         |
|                                                                   | Nasal                    | <input type="checkbox"/>         |
|                                                                   | Vaginal                  | <input type="checkbox"/>         |
|                                                                   | Rectal                   | <input type="checkbox"/>         |
|                                                                   | Intravenous              | <input type="checkbox"/>         |
|                                                                   | Intravenous Bolus        | <input type="checkbox"/>         |
|                                                                   | Intravenous Drip         | <input type="checkbox"/>         |
|                                                                   | Other                    | <input type="checkbox"/>         |
| <hr/>                                                             |                          |                                  |
| If route of administration is Other, specify <input type="text"/> |                          |                                  |
| <hr/>                                                             |                          |                                  |
| Start date (dd MMM yyyy)                                          |                          | 20 OCT 2020                      |
| Start date completely unknown                                     |                          | False                            |
| Ongoing?                                                          | Yes                      | <input checked="" type="radio"/> |
|                                                                   | No                       | <input type="radio"/>            |
| <hr/>                                                             |                          |                                  |
| If not Ongoing, End date (dd MMM yyyy) <input type="text"/>       |                          |                                  |
| <hr/>                                                             |                          |                                  |
| Was this medication taken for solicited event?                    | Yes                      | <input type="radio"/>            |
|                                                                   | No                       | <input checked="" type="radio"/> |
| <hr/>                                                             |                          |                                  |
| Separate Dosage Number (derived)                                  |                          | <input type="text"/>             |
| Interval Dosage Unit Number (derived)                             |                          | <input type="text"/>             |
| Interval Dosage Definition (derived)                              | 802                      | <input type="radio"/>            |
|                                                                   | 803                      | <input type="radio"/>            |
|                                                                   | 804                      | <input type="radio"/>            |



US3742169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:15:04

|                                      |                                                                                                                                                                                                                                                                                                                                                                                                                          |
|--------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Name of Medication                   | FLU VACCINE                                                                                                                                                                                                                                                                                                                                                                                                              |
| Prophylaxis                          | Yes <input checked="" type="radio"/><br>No <input type="radio"/>                                                                                                                                                                                                                                                                                                                                                         |
| Indication                           | VIRAL ILLNESS UNSPECIFIED                                                                                                                                                                                                                                                                                                                                                                                                |
| Dose per administration              | 0.5                                                                                                                                                                                                                                                                                                                                                                                                                      |
| Dose unit                            | mg <input type="radio"/><br>ug <input type="radio"/><br>mL <input checked="" type="radio"/><br>g <input type="radio"/><br>IU <input type="radio"/><br>tablet <input type="radio"/><br>capsule <input type="radio"/><br>puff <input type="radio"/><br>Other <input type="radio"/>                                                                                                                                         |
| If dose unit is Other, specify _____ |                                                                                                                                                                                                                                                                                                                                                                                                                          |
| Frequency                            | once daily <input type="radio"/><br>twice daily <input type="radio"/><br>three times daily <input type="radio"/><br>four times daily <input type="radio"/><br>every other day <input type="radio"/><br>every week <input type="radio"/><br>every month <input type="radio"/><br>as needed <input type="radio"/><br>once <input checked="" type="radio"/><br>unknown <input type="radio"/><br>other <input type="radio"/> |
| If frequency is Other, specify _____ |                                                                                                                                                                                                                                                                                                                                                                                                                          |
| Route of administration              | Oral <input type="radio"/><br>Topical <input type="radio"/><br>Subcutaneous <input type="radio"/><br>Transdermal <input type="radio"/><br>Intraocular <input type="radio"/><br>Intramuscular <input checked="" type="radio"/>                                                                                                                                                                                            |

US3742169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:15:04

|                                                                   |                          |                                     |
|-------------------------------------------------------------------|--------------------------|-------------------------------------|
|                                                                   | Respiratory (Inhalation) | <input type="checkbox"/>            |
|                                                                   | Intralesional            | <input type="checkbox"/>            |
|                                                                   | Intraperitoneal          | <input type="checkbox"/>            |
|                                                                   | Nasal                    | <input type="checkbox"/>            |
|                                                                   | Vaginal                  | <input type="checkbox"/>            |
|                                                                   | Rectal                   | <input type="checkbox"/>            |
|                                                                   | Intravenous              | <input type="checkbox"/>            |
|                                                                   | Intravenous Bolus        | <input type="checkbox"/>            |
|                                                                   | Intravenous Drip         | <input type="checkbox"/>            |
|                                                                   | Other                    | <input type="checkbox"/>            |
| <hr/>                                                             |                          |                                     |
| If route of administration is Other, specify <input type="text"/> |                          |                                     |
| <hr/>                                                             |                          |                                     |
| Start date (dd MMM yyyy)                                          |                          | 02 NOV 2020                         |
| Start date completely unknown                                     |                          | False                               |
| Ongoing?                                                          | Yes                      | <input type="checkbox"/>            |
|                                                                   | No                       | <input checked="" type="checkbox"/> |
| <hr/>                                                             |                          |                                     |
| If not Ongoing, End date (dd MMM yyyy)                            |                          | 02 NOV 2020                         |
| <hr/>                                                             |                          |                                     |
| Was this medication taken for solicited event?                    | Yes                      | <input type="checkbox"/>            |
|                                                                   | No                       | <input checked="" type="checkbox"/> |
| <hr/>                                                             |                          |                                     |
| Separate Dosage Number (derived)                                  |                          | <input type="text"/>                |
| Interval Dosage Unit Number (derived)                             |                          | <input type="text"/>                |
| Interval Dosage Definition (derived)                              |                          | 802 <input type="checkbox"/>        |
|                                                                   |                          | 803 <input type="checkbox"/>        |
|                                                                   |                          | 804 <input type="checkbox"/>        |

US3742169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:15:04

|                                |                                                                                                                                                                                                                                                                                                                                                                                                                          |
|--------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Name of Medication             | XYZAL                                                                                                                                                                                                                                                                                                                                                                                                                    |
| Prophylaxis                    | Yes <input type="radio"/><br>No <input checked="" type="radio"/>                                                                                                                                                                                                                                                                                                                                                         |
| Indication                     | VIRAL ILLNESS UNSPECIFIED                                                                                                                                                                                                                                                                                                                                                                                                |
| Dose per administration        | 3.75                                                                                                                                                                                                                                                                                                                                                                                                                     |
| Dose unit                      | mg <input checked="" type="radio"/><br>ug <input type="radio"/><br>mL <input type="radio"/><br>g <input type="radio"/><br>IU <input type="radio"/><br>tablet <input type="radio"/><br>capsule <input type="radio"/><br>puff <input type="radio"/><br>Other <input type="radio"/>                                                                                                                                         |
| If dose unit is Other, specify |                                                                                                                                                                                                                                                                                                                                                                                                                          |
| Frequency                      | once daily <input type="radio"/><br>twice daily <input type="radio"/><br>three times daily <input type="radio"/><br>four times daily <input type="radio"/><br>every other day <input type="radio"/><br>every week <input type="radio"/><br>every month <input type="radio"/><br>as needed <input checked="" type="radio"/><br>once <input type="radio"/><br>unknown <input type="radio"/><br>other <input type="radio"/> |
| If frequency is Other, specify |                                                                                                                                                                                                                                                                                                                                                                                                                          |
| Route of administration        | Oral <input checked="" type="radio"/><br>Topical <input type="radio"/><br>Subcutaneous <input type="radio"/><br>Transdermal <input type="radio"/><br>Intraocular <input type="radio"/><br>Intramuscular <input type="radio"/>                                                                                                                                                                                            |

US3742169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:15:04

|                                                                   |                          |                                     |
|-------------------------------------------------------------------|--------------------------|-------------------------------------|
|                                                                   | Respiratory (Inhalation) | <input type="checkbox"/>            |
|                                                                   | Intralesional            | <input type="checkbox"/>            |
|                                                                   | Intraperitoneal          | <input type="checkbox"/>            |
|                                                                   | Nasal                    | <input type="checkbox"/>            |
|                                                                   | Vaginal                  | <input type="checkbox"/>            |
|                                                                   | Rectal                   | <input type="checkbox"/>            |
|                                                                   | Intravenous              | <input type="checkbox"/>            |
|                                                                   | Intravenous Bolus        | <input type="checkbox"/>            |
|                                                                   | Intravenous Drip         | <input type="checkbox"/>            |
|                                                                   | Other                    | <input type="checkbox"/>            |
| <hr/>                                                             |                          |                                     |
| If route of administration is Other, specify <input type="text"/> |                          |                                     |
| <hr/>                                                             |                          |                                     |
| Start date (dd MMM yyyy)                                          |                          | 31 OCT 2020                         |
| Start date completely unknown                                     |                          | False                               |
| Ongoing?                                                          | Yes                      | <input type="checkbox"/>            |
|                                                                   | No                       | <input checked="" type="checkbox"/> |
| <hr/>                                                             |                          |                                     |
| If not Ongoing, End date (dd MMM yyyy)                            |                          | 14 NOV 2020                         |
| Was this medication taken for solicited event?                    | Yes                      | <input type="checkbox"/>            |
|                                                                   | No                       | <input checked="" type="checkbox"/> |
| <hr/>                                                             |                          |                                     |
| Separate Dosage Number (derived)                                  |                          | <input type="text"/>                |
| Interval Dosage Unit Number (derived)                             |                          | <input type="text"/>                |
| Interval Dosage Definition (derived)                              | 802                      | <input type="checkbox"/>            |
|                                                                   | 803                      | <input type="checkbox"/>            |
|                                                                   | 804                      | <input type="checkbox"/>            |

US3742169

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures Summary**

**Generated On: 26 Nov 2020 11:15:04**

---

Were any concomitant procedures performed?

Yes ☐

No ☐

---

**If yes, please complete Concomitant Procedures form.**

---

US3742169

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 11:15:04

Date of dosing discontinuation (dd MMM yyyy)

3 OCT 2020

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☒

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by  
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

If reason is AE, SAE, Physician Decision, Withdrawal of consent  
by participant, Protocol deviation, or Other, specify

SAE (AE#2)

US3742169

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 11:15:04

Date of study discontinuation/completion (dd MMM yyyy)

Reason for discontinuation

AE (specify) ☐

SAE (specify) ☐

Complete ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by ☐

participant (specify)

Other ☐

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

If reason for discontinuation is Death, main cause of death

Adverse event ☐

Unknown ☐

Other ☐

If main cause of death is Other, specify

Date of death (dd MMM yyyy)

Was autopsy performed?

Yes ☐

No ☐

Unknown ☐

US3742169

Folder: SAE USA-US127-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:04

|                                                                |                                                                  |
|----------------------------------------------------------------|------------------------------------------------------------------|
| SAEID                                                          | USA-US127-2020-MRNA-1273-P301000003                              |
| Serious                                                        | Yes <input checked="" type="radio"/><br>No <input type="radio"/> |
| Death                                                          | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Life threatening                                               | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Requires inpatient or prolongation of existing Hospitalization | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Persistent or significant disability or incapacity             | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Congenital anomaly or birth defect                             | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Other medically important event                                | Yes <input checked="" type="radio"/><br>No <input type="radio"/> |
| Investigator's First Name                                      | KAREN                                                            |
| Investigator's Last Name                                       | KOTLOFF                                                          |
| Site Address: Street                                           | 685 W. BALTIMORE STREET,<br>HSF 480                              |
| Site Address: City                                             | BALTIMORE                                                        |
| Site Address: State                                            |                                                                  |
| Site Address: Postal Code                                      | 21201                                                            |
| Investigator Country                                           | US                                                               |
| E2B Transmit Flag (Derived/Hidden)                             | 5                                                                |



US3742169

Folder: SAE USA-US127-2020-MRNA-1273-P301000003

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 11:15:04

|                                                                                                                                                                                               |                                                                  |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------|
| SAEID                                                                                                                                                                                         | USA-US127-2020-MRNA-1273-P301000003                              |
| Serious                                                                                                                                                                                       | Yes <input checked="" type="radio"/><br>No <input type="radio"/> |
| Death                                                                                                                                                                                         | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Life threatening                                                                                                                                                                              | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Requires inpatient or prolongation of existing Hospitalization                                                                                                                                | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Persistent or significant disability or incapacity                                                                                                                                            | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Congenital anomaly or birth defect                                                                                                                                                            | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Other medically important event                                                                                                                                                               | Yes <input checked="" type="radio"/><br>No <input type="radio"/> |
| Investigator's First Name                                                                                                                                                                     | KAREN                                                            |
| Investigator's Last Name                                                                                                                                                                      | KOTLOFF                                                          |
| Site Address: Street                                                                                                                                                                          | 685 W. BALTIMORE STREET,<br>HSF 480                              |
| Site Address: City                                                                                                                                                                            | BALTIMORE                                                        |
| Site Address: State                                                                                                                                                                           |                                                                  |
| Site Address: Postal Code                                                                                                                                                                     | 21201                                                            |
| Investigator Country                                                                                                                                                                          | US                                                               |
| E2B Transmit Flag (Derived/Hidden)                                                                                                                                                            | 5                                                                |
| Date of submission (Pre-filled from custom function)                                                                                                                                          | 05/OCT/2020 13:32                                                |
| Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge. | True                                                             |

US3742169

Folder: SAE USA-US127-2020-MRNA-1273-P301000003

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 11:15:04

|                                                                                                                                                                                               |                                                                  |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------|
| SAEID                                                                                                                                                                                         | USA-US127-2020-MRNA-1273-P301000003                              |
| Serious                                                                                                                                                                                       | Yes <input checked="" type="radio"/><br>No <input type="radio"/> |
| Death                                                                                                                                                                                         | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Life threatening                                                                                                                                                                              | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Requires inpatient or prolongation of existing Hospitalization                                                                                                                                | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Persistent or significant disability or incapacity                                                                                                                                            | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Congenital anomaly or birth defect                                                                                                                                                            | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Other medically important event                                                                                                                                                               | Yes <input checked="" type="radio"/><br>No <input type="radio"/> |
| Investigator's First Name                                                                                                                                                                     | KAREN                                                            |
| Investigator's Last Name                                                                                                                                                                      | KOTLOFF                                                          |
| Site Address: Street                                                                                                                                                                          | 685 W. BALTIMORE STREET,<br>HSF 480                              |
| Site Address: City                                                                                                                                                                            | BALTIMORE                                                        |
| Site Address: State                                                                                                                                                                           |                                                                  |
| Site Address: Postal Code                                                                                                                                                                     | 21201                                                            |
| Investigator Country                                                                                                                                                                          | US                                                               |
| E2B Transmit Flag (Derived/Hidden)                                                                                                                                                            | 5                                                                |
| Date of submission (Pre-filled from custom function)                                                                                                                                          | 15/OCT/2020 08:41                                                |
| Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge. | True                                                             |

US3742169

Folder: SAE USA-US127-2020-MRNA-1273-P301000003

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 11:15:04

|                                                                                                                                                                                               |                                                               |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------|
| SAEID                                                                                                                                                                                         | USA-US127-2020-MRNA-1273-P301000003                           |
| Serious                                                                                                                                                                                       | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Death                                                                                                                                                                                         | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Life threatening                                                                                                                                                                              | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Requires inpatient or prolongation of existing Hospitalization                                                                                                                                | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Persistent or significant disability or incapacity                                                                                                                                            | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Congenital anomaly or birth defect                                                                                                                                                            | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Other medically important event                                                                                                                                                               | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Investigator's First Name                                                                                                                                                                     | KAREN                                                         |
| Investigator's Last Name                                                                                                                                                                      | KOTLOFF                                                       |
| Site Address: Street                                                                                                                                                                          | 685 W. BALTIMORE STREET,<br>HSF 480                           |
| Site Address: City                                                                                                                                                                            | BALTIMORE                                                     |
| Site Address: State                                                                                                                                                                           |                                                               |
| Site Address: Postal Code                                                                                                                                                                     | 21201                                                         |
| Investigator Country                                                                                                                                                                          | US                                                            |
| E2B Transmit Flag (Derived/Hidden)                                                                                                                                                            | 5                                                             |
| Date of submission (Pre-filled from custom function)                                                                                                                                          | 15/OCT/2020 20:38                                             |
| Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge. | True                                                          |

US3742169

Folder: SAE USA-US127-2020-MRNA-1273-P301000003

Form: Safety Report Form (4)

Generated On: 26 Nov 2020 11:15:04

|                                                                                                                                                                                               |                                                                  |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------|
| SAEID                                                                                                                                                                                         | USA-US127-2020-MRNA-1273-P301000003                              |
| Serious                                                                                                                                                                                       | Yes <input checked="" type="radio"/><br>No <input type="radio"/> |
| Death                                                                                                                                                                                         | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Life threatening                                                                                                                                                                              | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Requires inpatient or prolongation of existing Hospitalization                                                                                                                                | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Persistent or significant disability or incapacity                                                                                                                                            | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Congenital anomaly or birth defect                                                                                                                                                            | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Other medically important event                                                                                                                                                               | Yes <input checked="" type="radio"/><br>No <input type="radio"/> |
| Investigator's First Name                                                                                                                                                                     | KAREN                                                            |
| Investigator's Last Name                                                                                                                                                                      | KOTLOFF                                                          |
| Site Address: Street                                                                                                                                                                          | 685 W. BALTIMORE STREET,<br>HSF 480                              |
| Site Address: City                                                                                                                                                                            | BALTIMORE                                                        |
| Site Address: State                                                                                                                                                                           |                                                                  |
| Site Address: Postal Code                                                                                                                                                                     | 21201                                                            |
| Investigator Country                                                                                                                                                                          | US                                                               |
| E2B Transmit Flag (Derived/Hidden)                                                                                                                                                            | 5                                                                |
| Date of submission (Pre-filled from custom function)                                                                                                                                          | 10/NOV/2020 14:11                                                |
| Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge. | True                                                             |

US3742169

Folder: SAE USA-US127-2020-MRNA-1273-P301000003

Form: Safety Report Form (5)

Generated On: 26 Nov 2020 11:15:04

|                                                                                                                                                                                               |                                                                  |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------|
| SAEID                                                                                                                                                                                         | USA-US127-2020-MRNA-1273-P301000003                              |
| Serious                                                                                                                                                                                       | Yes <input checked="" type="radio"/><br>No <input type="radio"/> |
| Death                                                                                                                                                                                         | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Life threatening                                                                                                                                                                              | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Requires inpatient or prolongation of existing Hospitalization                                                                                                                                | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Persistent or significant disability or incapacity                                                                                                                                            | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Congenital anomaly or birth defect                                                                                                                                                            | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Other medically important event                                                                                                                                                               | Yes <input checked="" type="radio"/><br>No <input type="radio"/> |
| Investigator's First Name                                                                                                                                                                     | KAREN                                                            |
| Investigator's Last Name                                                                                                                                                                      | KOTLOFF                                                          |
| Site Address: Street                                                                                                                                                                          | 685 W. BALTIMORE STREET,<br>HSF 480                              |
| Site Address: City                                                                                                                                                                            | BALTIMORE                                                        |
| Site Address: State                                                                                                                                                                           |                                                                  |
| Site Address: Postal Code                                                                                                                                                                     | 21201                                                            |
| Investigator Country                                                                                                                                                                          | US                                                               |
| E2B Transmit Flag (Derived/Hidden)                                                                                                                                                            | 5                                                                |
| Date of submission (Pre-filled from custom function)                                                                                                                                          | 24/NOV/2020 08:31                                                |
| Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge. | True                                                             |

Audit

US3742169 (Prod: University of Maryland School of Medicine)

**US3742169**

**Form: Participant Creation**

**Generated On: 26 Nov 2020 11:15:04**

[Participant ID](#)

| Audit                    | User                             | Time (GMT)           |
|--------------------------|----------------------------------|----------------------|
| DataPoint Verified.      | (b) (4), (b) (6)                 | 28 Oct 2020 15:58:16 |
| User entered 'US3742169' | RWS_ENDPOINT<br>ENDPOINT (b) (4) | 31 Aug 2020 11:54:28 |

US3742169

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:15:04

[Was this visit performed?](#)

| Audit                  | User                           | Time (GMT)           |
|------------------------|--------------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)               | 01 Oct 2020 20:15:13 |
| User entered 'Yes (Y)' | Hassan Haji (b) (4)<br>(b) (4) | 31 Aug 2020 13:35:31 |



US3742169

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:15:04

[Visit date \(dd MMM yyyy\)](#)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                 | 01 Oct 2020 20:15:13 |
| User entered '31 AUG 2020' | RWS_ENDPOINT<br>ENDPOINT (b) (4) | 31 Aug 2020 11:54:29 |

US3742169

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:15:04

[Was visit performed at the participant's home or at the clinic?](#)

| Audit                          | User                           | Time (GMT)           |
|--------------------------------|--------------------------------|----------------------|
| DataPoint Verified.            | (b) (4), (b) (6)               | 01 Oct 2020 20:15:13 |
| User entered 'Clinic (Clinic)' | Hassan Haji (b) (4)<br>(b) (4) | 31 Aug 2020 13:35:31 |

**US3742169**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 26 Nov 2020 11:15:04**

[Folder OID](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'SCRN' | System | 31 Aug 2020 13:35:31 |

US3742169

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:15:04

Date of Birth (MMM yyyy)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                 | 01 Oct 2020 20:16:14 |
| User entered (b) (6) 1963' | RWS_ENDPOINT<br>ENDPOINT (b) (4) | 31 Aug 2020 11:54:30 |

US3742169

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:15:04

[Age](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 01 Oct 2020 20:16:16 |
| User entered '57'   | Hassan Haji (b) (4)<br>(b) (4) | 31 Aug 2020 13:35:58 |

US3742169

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 11:15:04**

[Age Units](#)

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| User entered 'YEARS' | System | 31 Aug 2020 13:35:58 |

US3742169

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 11:15:04**

[Age \(Derived\)](#)

| Audit             | User   | Time (GMT)           |
|-------------------|--------|----------------------|
| User entered '57' | System | 31 Aug 2020 13:36:44 |

US3742169

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:15:04

Sex

| Audit                   | User                           | Time (GMT)           |
|-------------------------|--------------------------------|----------------------|
| DataPoint Verified.     | (b) (4), (b) (6)               | 01 Oct 2020 20:16:18 |
| User entered 'Male (M)' | Hassan Haji (b) (4)<br>(b) (4) | 31 Aug 2020 13:35:58 |



US3742169

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:15:04

[Ethnicity](#)

| Audit                                                          | User                           | Time (GMT)           |
|----------------------------------------------------------------|--------------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)               | 01 Oct 2020 20:16:20 |
| User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)' | Hassan Haji (b) (4)<br>(b) (4) | 31 Aug 2020 13:35:58 |

US3742169

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:15:04

[White](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 01 Oct 2020 20:16:22 |
| User entered '0'    | Hassan Haji (b) (4)<br>(b) (4) | 31 Aug 2020 13:35:58 |

US3742169

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:15:04

[Black](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 01 Oct 2020 20:16:24 |
| User entered '0'    | Hassan Haji (b) (4)<br>(b) (4) | 31 Aug 2020 13:35:58 |

US3742169

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:15:04

[Asian](#)

| Audit                                                | User                  | Time (GMT)           |
|------------------------------------------------------|-----------------------|----------------------|
| DataPoint Verified.                                  | (b) (4), (b) (6)      | 28 Oct 2020 16:00:20 |
| User entered '1' reason for change: Data Entry Error | Kaitlin Mason (b) (4) | 05 Oct 2020 17:50:31 |
| User entered '0'                                     | Hassan Haji (b) (4)   | 31 Aug 2020 13:35:58 |

US3742169

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:15:04

[American Indian or Alaska Native](#)

| Audit                                                                                                                    | User                             | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------|----------------------------------|----------------------|
| DataPoint Verified.                                                                                                      | (b) (4), (b) (6)                 | 28 Oct 2020 16:00:20 |
| User closed query 'Source states race as Asian. Please verify if correct slot is ticked.' (Site from CRA).               | (b) (4), (b) (6)                 | 23 Oct 2020 14:05:42 |
| Query 'Source states race as Asian. Please verify if correct slot is ticked.' answered with 'CORRECTED' (Site from CRA). | Kaitlin Mason (b) (4)<br>(b) (4) | 05 Oct 2020 17:50:41 |
| User entered '0' reason for change: Data Entry Error                                                                     | Kaitlin Mason (b) (4)<br>(b) (4) | 05 Oct 2020 17:50:31 |
| User opened query 'Source states race as Asian. Please verify if correct slot is ticked.' (Site from CRA).               | (b) (4), (b) (6)                 | 01 Oct 2020 20:16:07 |
| User entered '1'                                                                                                         | Hassan Haji (b) (4)<br>(b) (4)   | 31 Aug 2020 13:35:58 |

US3742169

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 11:15:04**

[Native Hawaiian or other Pacific Islander](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 01 Oct 2020 20:16:27 |
| User entered '0'    | Hassan Haji (b) (4)<br>(b) (4) | 31 Aug 2020 13:35:58 |

US3742169

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:15:04

[Other](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 01 Oct 2020 20:16:28 |
| User entered '0'    | Hassan Haji (b) (4)<br>(b) (4) | 31 Aug 2020 13:35:58 |

US3742169

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:15:04

[If race is Other, specify](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 01 Oct 2020 20:16:30 |
| User entered empty. | Hassan Haji (b) (4)<br>(b) (4) | 31 Aug 2020 13:35:58 |



US3742169

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:15:04

[Unknown](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 01 Oct 2020 20:16:31 |
| User entered '0'    | Hassan Haji (b) (4)<br>(b) (4) | 31 Aug 2020 13:35:58 |

US3742169

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:15:04

[Not reported](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 01 Oct 2020 20:16:33 |
| User entered '0'    | Hassan Haji (b) (4)<br>(b) (4) | 31 Aug 2020 13:35:58 |

US3742169

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 11:15:04**

[Date of Informed Consent \(dd MMM yyyy\)](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 01 Oct 2020 20:19:12 |
| User entered '31 Aug 2020' | Hassan Haji (b) (4)<br>(b) (4) | 31 Aug 2020 13:36:44 |

US3742169

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 11:15:04**

[Month and Year of Informed Consent \(derived\)](#)

| Audit                   | User   | Time (GMT)           |
|-------------------------|--------|----------------------|
| User entered 'Aug 2020' | System | 31 Aug 2020 13:36:44 |

US3742169

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 11:15:04**

[Year of Informed Consent \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '2020' | System | 31 Aug 2020 13:36:44 |

US3742169

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 11:15:04**

[Protocol Version](#)

| Audit                          | User                           | Time (GMT)           |
|--------------------------------|--------------------------------|----------------------|
| DataPoint Verified.            | (b) (4), (b) (6)               | 01 Oct 2020 20:19:12 |
| User entered 'Amendment 3 (3)' | Hassan Haji (b) (4)<br>(b) (4) | 31 Aug 2020 13:36:44 |

US3742169

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 11:15:04**

[Was participant enrolled in the study?](#)

| Audit                  | User                           | Time (GMT)           |
|------------------------|--------------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)               | 01 Oct 2020 20:19:12 |
| User entered 'Yes (Y)' | Hassan Haji (b) (4)<br>(b) (4) | 31 Aug 2020 13:36:44 |

US3742169

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 11:15:04**

[If No, indicate reason for screen fail](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 01 Oct 2020 20:19:12 |
| User entered empty. | Hassan Haji (b) (4)<br>(b) (4) | 31 Aug 2020 13:36:44 |



US3742169

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 11:15:04**

If reason for screen fail is Other, specify

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 01 Oct 2020 20:19:12 |
| User entered empty. | Hassan Haji (b) (4)<br>(b) (4) | 31 Aug 2020 13:36:44 |

US3742169

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 11:15:04**

[Was this participant screened previously?](#)

| Audit                 | User                           | Time (GMT)           |
|-----------------------|--------------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)               | 01 Oct 2020 20:19:12 |
| User entered 'No (N)' | Hassan Haji (b) (4)<br>(b) (4) | 31 Aug 2020 13:36:44 |

US3742169

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:15:04

[If Yes, previous participant number](#)

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                 | 01 Oct 2020 20:19:12 |
| User entered empty. | RWS_ENDPOINT<br>ENDPOINT (b) (4) | 31 Aug 2020 11:54:29 |

US3742169

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 11:15:04**

[Enrollment Trigger](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 31 Aug 2020 13:36:49 |

US3742169

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 11:15:04

[Did the participant meet all eligibility criteria?](#)

| Audit                  | User                           | Time (GMT)           |
|------------------------|--------------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)               | 01 Oct 2020 20:19:17 |
| User entered 'Yes (Y)' | Hassan Haji (b) (4)<br>(b) (4) | 31 Aug 2020 13:36:49 |

US3742169

Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 11:15:04

[Were any significant conditions reported?](#)

| Audit                  | User                           | Time (GMT)           |
|------------------------|--------------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)               | 01 Oct 2020 20:19:22 |
| User entered 'Yes (Y)' | Hassan Haji (b) (4)<br>(b) (4) | 31 Aug 2020 17:27:13 |

US3742169

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:15:04

[Condition](#)

| Audit                                                                                                                                                                                                                                                                                  | User                            | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------|----------------------|
| DataPoint Verified.                                                                                                                                                                                                                                                                    | (b) (4), (b) (6)                | 01 Oct 2020 20:19:41 |
| User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastrooesophageal reflux disease, LLT: Gastrooesophageal reflux disease - version MedDRA\\23.0. | Coder Import (b) (4)<br>(b) (4) | 31 Aug 2020 17:33:38 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.                                                                                                                                                                                           | Coder Import (b) (4)<br>(b) (4) | 31 Aug 2020 17:33:38 |
| Data point term sent to Coder                                                                                                                                                                                                                                                          | System                          | 31 Aug 2020 17:32:55 |
| User entered 'gastroesophageal reflux disease'                                                                                                                                                                                                                                         | Hassan Haji (b) (4)<br>(b) (4)  | 31 Aug 2020 17:32:22 |

US3742169

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:15:04

[Start date \(dd MMM yyyy\)](#)

| Audit                                                             | User                             | Time (GMT)           |
|-------------------------------------------------------------------|----------------------------------|----------------------|
| DataPoint Verified.                                               | (b) (4), (b) (6)                 | 01 Oct 2020 20:19:41 |
| User entered 'UN UNK 2010' reason for change:<br>Data Entry Error | Kaitlin Mason (b) (4)<br>(b) (4) | 11 Sep 2020 22:56:35 |
| User entered '30 Jun 2010'                                        | Hassan Haji (b) (4)<br>(b) (4)   | 31 Aug 2020 17:32:22 |



US3742169

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:15:04

[Start date completely unknown](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 01 Oct 2020 20:19:41 |
| User entered '0'    | Hassan Haji (b) (4)<br>(b) (4) | 31 Aug 2020 17:32:22 |

US3742169

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:15:04

[Condition ongoing at study entry](#)

| Audit                  | User                           | Time (GMT)           |
|------------------------|--------------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)               | 01 Oct 2020 20:19:41 |
| User entered 'Yes (Y)' | Hassan Haji (b) (4)<br>(b) (4) | 31 Aug 2020 17:32:22 |

US3742169

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 11:15:04**

If No, please specify the stop date (dd MMM yyyy)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 01 Oct 2020 20:19:41 |
| User entered empty. | Hassan Haji (b) (4)<br>(b) (4) | 31 Aug 2020 17:32:22 |

US3742169

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:15:04

[Stop date completely unknown](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 01 Oct 2020 20:19:41 |
| User entered '0'    | Hassan Haji (b) (4)<br>(b) (4) | 31 Aug 2020 17:32:22 |

US3742169

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 11:15:04**

[Start Month and Year \(derived\)](#)

| Audit                   | User   | Time (GMT)           |
|-------------------------|--------|----------------------|
| User entered 'Jan 2010' | System | 11 Sep 2020 22:56:35 |
| User entered 'Jun 2010' | System | 31 Aug 2020 17:32:22 |

US3742169

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 11:15:04**

[Start Year \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '2010' | System | 31 Aug 2020 17:32:22 |

US3742169

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 11:15:04**

[Stop Month and Year \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 31 Aug 2020 17:32:22 |

US3742169

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 11:15:04**

[Stop Year \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 31 Aug 2020 17:32:22 |



US3742169

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:15:04

[Condition](#)

| Audit                                                                                                                                                                                  | User                 | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|----------------------|
| DataPoint Verified.                                                                                                                                                                    | (b) (4), (b) (6)     | 01 Oct 2020 20:19:41 |
| User coded data point as SOC: Endocrine disorders, HLGT: Thyroid gland disorders, HLT: Thyroid hypofunction disorders, PT: Hypothyroidism, LLT: Hypothyroidism - version MedDRA\\23.0. | Coder Import (b) (4) | 31 Aug 2020 17:34:40 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.                                                                                           | (b) (4)              | 31 Aug 2020 17:34:40 |
| Data point term sent to Coder                                                                                                                                                          | System               | 31 Aug 2020 17:33:57 |
| User entered 'hypothyroidism'                                                                                                                                                          | Hassan Haji (b) (4)  | 31 Aug 2020 17:33:16 |
|                                                                                                                                                                                        | (b) (4)              |                      |

US3742169

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:15:04

[Start date \(dd MMM yyyy\)](#)

| Audit                                                             | User                             | Time (GMT)           |
|-------------------------------------------------------------------|----------------------------------|----------------------|
| DataPoint Verified.                                               | (b) (4), (b) (6)                 | 01 Oct 2020 20:19:41 |
| User entered 'UN UNK 1990' reason for change:<br>Data Entry Error | Kaitlin Mason (b) (4)<br>(b) (4) | 11 Sep 2020 22:56:48 |
| User entered '30 Jun 1990'                                        | Hassan Haji (b) (4)<br>(b) (4)   | 31 Aug 2020 17:33:16 |

US3742169

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:15:04

[Start date completely unknown](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 01 Oct 2020 20:19:41 |
| User entered '0'    | Hassan Haji (b) (4)<br>(b) (4) | 31 Aug 2020 17:33:16 |

US3742169

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:15:04

[Condition ongoing at study entry](#)

| Audit                  | User                           | Time (GMT)           |
|------------------------|--------------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)               | 01 Oct 2020 20:19:41 |
| User entered 'Yes (Y)' | Hassan Haji (b) (4)<br>(b) (4) | 31 Aug 2020 17:33:16 |

US3742169

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:15:04

If No, please specify the stop date (dd MMM yyyy)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 01 Oct 2020 20:19:41 |
| User entered empty. | Hassan Haji (b) (4)<br>(b) (4) | 31 Aug 2020 17:33:16 |

US3742169

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 11:15:04**

[Stop date completely unknown](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 01 Oct 2020 20:19:41 |
| User entered '0'    | Hassan Haji (b) (4)<br>(b) (4) | 31 Aug 2020 17:33:16 |

US3742169

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 11:15:04**

[Start Month and Year \(derived\)](#)

| Audit                   | User   | Time (GMT)           |
|-------------------------|--------|----------------------|
| User entered 'Jan 1990' | System | 11 Sep 2020 22:56:48 |
| User entered 'Jun 1990' | System | 31 Aug 2020 17:33:16 |

US3742169

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 11:15:04**

[Start Year \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '1990' | System | 31 Aug 2020 17:33:16 |



US3742169

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 11:15:04**

[Stop Month and Year \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 31 Aug 2020 17:33:16 |

US3742169

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 11:15:04**

[Stop Year \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 31 Aug 2020 17:33:16 |

US3742169

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:15:04

[Condition](#)

| Audit                                                                                                                                                                                          | User                            | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------|----------------------|
| DataPoint Verified.                                                                                                                                                                            | (b) (4), (b) (6)                | 01 Oct 2020 20:19:41 |
| User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0. | Coder Import (b) (4)<br>(b) (4) | 31 Aug 2020 17:35:43 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.                                                                                                   | Coder Import (b) (4)<br>(b) (4) | 31 Aug 2020 17:35:43 |
| Data point term sent to Coder                                                                                                                                                                  | System                          | 31 Aug 2020 17:34:57 |
| User entered 'hypertension'                                                                                                                                                                    | Hassan Haji (b) (4)<br>(b) (4)  | 31 Aug 2020 17:34:08 |

US3742169

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:15:04

[Start date \(dd MMM yyyy\)](#)

| Audit                                                             | User                             | Time (GMT)           |
|-------------------------------------------------------------------|----------------------------------|----------------------|
| DataPoint Verified.                                               | (b) (4), (b) (6)                 | 01 Oct 2020 20:19:41 |
| User entered 'UN UNK 2018' reason for change:<br>Data Entry Error | Kaitlin Mason (b) (4)<br>(b) (4) | 11 Sep 2020 22:56:58 |
| User entered '30 Jun 2018'                                        | Hassan Haji (b) (4)<br>(b) (4)   | 31 Aug 2020 17:34:08 |

US3742169

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 11:15:04**

[Start date completely unknown](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 01 Oct 2020 20:19:41 |
| User entered '0'    | Hassan Haji (b) (4)<br>(b) (4) | 31 Aug 2020 17:34:08 |

US3742169

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:15:04

[Condition ongoing at study entry](#)

| Audit                  | User                           | Time (GMT)           |
|------------------------|--------------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)               | 01 Oct 2020 20:19:41 |
| User entered 'Yes (Y)' | Hassan Haji (b) (4)<br>(b) (4) | 31 Aug 2020 17:34:08 |

US3742169

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:15:04

If No, please specify the stop date (dd MMM yyyy)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 01 Oct 2020 20:19:41 |
| User entered empty. | Hassan Haji (b) (4)<br>(b) (4) | 31 Aug 2020 17:34:08 |

US3742169

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:15:04

[Stop date completely unknown](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 01 Oct 2020 20:19:41 |
| User entered '0'    | Hassan Haji (b) (4)<br>(b) (4) | 31 Aug 2020 17:34:08 |



US3742169

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 11:15:04**

[Start Month and Year \(derived\)](#)

| Audit                   | User   | Time (GMT)           |
|-------------------------|--------|----------------------|
| User entered 'Jan 2018' | System | 11 Sep 2020 22:56:58 |
| User entered 'Jun 2018' | System | 31 Aug 2020 17:34:08 |

US3742169

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 11:15:04**

[Start Year \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '2018' | System | 31 Aug 2020 17:34:08 |

US3742169

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 11:15:04**

[Stop Month and Year \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 31 Aug 2020 17:34:08 |

US3742169

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 11:15:04**

[Stop Year \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 31 Aug 2020 17:34:08 |

US3742169

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:15:04

[Condition](#)

| Audit                                                                                                                                                                                                         | User                 | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|----------------------|
| DataPoint Verified.                                                                                                                                                                                           | (b) (4), (b) (6)     | 01 Oct 2020 20:19:41 |
| User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Asthma, LLT: Asthma - version MedDRA\\23.0. | Coder Import (b) (4) | 31 Aug 2020 17:35:44 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.                                                                                                                  | (b) (4)              | 31 Aug 2020 17:35:44 |
| Data point term sent to Coder                                                                                                                                                                                 | System               | 31 Aug 2020 17:34:58 |
| User entered 'asthma'                                                                                                                                                                                         | Hassan Haji (b) (4)  | 31 Aug 2020 17:34:39 |
|                                                                                                                                                                                                               | (b) (4)              |                      |

US3742169

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:15:04

[Start date \(dd MMM yyyy\)](#)

| Audit                                                             | User                             | Time (GMT)           |
|-------------------------------------------------------------------|----------------------------------|----------------------|
| DataPoint Verified.                                               | (b) (4), (b) (6)                 | 01 Oct 2020 20:19:41 |
| User entered 'UN UNK 2000' reason for change:<br>Data Entry Error | Kaitlin Mason (b) (4)<br>(b) (4) | 11 Sep 2020 22:57:16 |
| User entered '30 Jun 2000'                                        | Hassan Haji (b) (4)<br>(b) (4)   | 31 Aug 2020 17:34:39 |

US3742169

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 26 Nov 2020 11:15:04**

[Start date completely unknown](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 01 Oct 2020 20:19:41 |
| User entered '0'    | Hassan Haji (b) (4)<br>(b) (4) | 31 Aug 2020 17:34:39 |

US3742169

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 26 Nov 2020 11:15:04**

[Condition ongoing at study entry](#)

| Audit                  | User                           | Time (GMT)           |
|------------------------|--------------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)               | 01 Oct 2020 20:19:41 |
| User entered 'Yes (Y)' | Hassan Haji (b) (4)<br>(b) (4) | 31 Aug 2020 17:34:39 |



US3742169

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 26 Nov 2020 11:15:04**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 01 Oct 2020 20:19:41 |
| User entered empty. | Hassan Haji (b) (4)<br>(b) (4) | 31 Aug 2020 17:34:39 |

US3742169

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:15:04

[Stop date completely unknown](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 01 Oct 2020 20:19:41 |
| User entered '0'    | Hassan Haji (b) (4)<br>(b) (4) | 31 Aug 2020 17:34:39 |

US3742169

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 26 Nov 2020 11:15:04**

[Start Month and Year \(derived\)](#)

| Audit                   | User   | Time (GMT)           |
|-------------------------|--------|----------------------|
| User entered 'Jan 2000' | System | 11 Sep 2020 22:57:16 |
| User entered 'Jun 2000' | System | 31 Aug 2020 17:34:39 |

US3742169

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 26 Nov 2020 11:15:04**

[Start Year \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '2000' | System | 31 Aug 2020 17:34:39 |

US3742169

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 26 Nov 2020 11:15:04**

[Stop Month and Year \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 31 Aug 2020 17:34:39 |

US3742169

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 26 Nov 2020 11:15:04**

[Stop Year \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 31 Aug 2020 17:34:39 |

US3742169

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:15:04

[Condition](#)

| Audit                                                                                                                                                                                   | User                 | Time (GMT)           |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|----------------------|
| DataPoint Verified.                                                                                                                                                                     | (b) (4), (b) (6)     | 01 Oct 2020 20:19:41 |
| User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergic conditions NEC, PT: Hypersensitivity, LLT: Environmental allergy - version MedDRA\23.0. | Coder Import (b) (4) | 31 Aug 2020 17:36:32 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.                                                                                             | (b) (4)              | 31 Aug 2020 17:36:32 |
| Data point term sent to Coder                                                                                                                                                           | System               | 31 Aug 2020 17:36:02 |
| User entered 'environmental allergies'                                                                                                                                                  | Hassan Haji (b) (4)  | 31 Aug 2020 17:35:15 |
|                                                                                                                                                                                         | (b) (4)              |                      |

US3742169

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:15:04

[Start date \(dd MMM yyyy\)](#)

| Audit                                                             | User                             | Time (GMT)           |
|-------------------------------------------------------------------|----------------------------------|----------------------|
| DataPoint Verified.                                               | (b) (4), (b) (6)                 | 01 Oct 2020 20:19:41 |
| User entered 'UN UNK 1990' reason for change:<br>Data Entry Error | Kaitlin Mason (b) (4)<br>(b) (4) | 11 Sep 2020 22:57:26 |
| User entered '30 Jun 1990'                                        | Hassan Haji (b) (4)<br>(b) (4)   | 31 Aug 2020 17:35:15 |



US3742169

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 26 Nov 2020 11:15:04**

[Start date completely unknown](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 01 Oct 2020 20:19:41 |
| User entered '0'    | Hassan Haji (b) (4)<br>(b) (4) | 31 Aug 2020 17:35:15 |

US3742169

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:15:04

[Condition ongoing at study entry](#)

| Audit                  | User                           | Time (GMT)           |
|------------------------|--------------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)               | 01 Oct 2020 20:19:41 |
| User entered 'Yes (Y)' | Hassan Haji (b) (4)<br>(b) (4) | 31 Aug 2020 17:35:15 |

US3742169

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 26 Nov 2020 11:15:04**

If No, please specify the stop date (dd MMM yyyy)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 01 Oct 2020 20:19:41 |
| User entered empty. | Hassan Haji (b) (4)<br>(b) (4) | 31 Aug 2020 17:35:15 |

US3742169

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:15:04

[Stop date completely unknown](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 01 Oct 2020 20:19:41 |
| User entered '0'    | Hassan Haji (b) (4)<br>(b) (4) | 31 Aug 2020 17:35:15 |

US3742169

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 26 Nov 2020 11:15:04**

[Start Month and Year \(derived\)](#)

| Audit                   | User   | Time (GMT)           |
|-------------------------|--------|----------------------|
| User entered 'Jan 1990' | System | 11 Sep 2020 22:57:26 |
| User entered 'Jun 1990' | System | 31 Aug 2020 17:35:15 |

US3742169

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 26 Nov 2020 11:15:04**

[Start Year \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '1990' | System | 31 Aug 2020 17:35:15 |

US3742169

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 26 Nov 2020 11:15:04**

[Stop Month and Year \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 31 Aug 2020 17:35:15 |

US3742169

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 26 Nov 2020 11:15:04**

[Stop Year \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 31 Aug 2020 17:35:15 |



US3742169

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:15:04

[Condition](#)

| Audit                                                                                                                                                                                                                                                                       | User                             | Time (GMT)           |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------|----------------------|
| User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Pain in extremity, LLT: Pain in thigh - version MedDRA\\23.0. | Coder Import (b) (4)<br>(b) (4)  | 21 Nov 2020 09:04:46 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.                                                                                                                                                                                     | Coder Import (b) (4)<br>(b) (4)  | 21 Nov 2020 09:04:46 |
| Data point term sent to Coder                                                                                                                                                                                                                                               | System                           | 20 Nov 2020 18:00:31 |
| User entered 'Left outer thigh pain'                                                                                                                                                                                                                                        | Kaitlin Mason (b) (4)<br>(b) (4) | 20 Nov 2020 17:59:46 |

US3742169

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 26 Nov 2020 11:15:04**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| User entered 'UN Jan 2020' | Kaitlin Mason (b) (4)<br>(b) (4) | 20 Nov 2020 17:59:46 |

US3742169

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 26 Nov 2020 11:15:04**

[Start date completely unknown](#)

| Audit            | User                             | Time (GMT)           |
|------------------|----------------------------------|----------------------|
| User entered '0' | Kaitlin Mason (b) (4)<br>(b) (4) | 20 Nov 2020 17:59:46 |

US3742169

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 26 Nov 2020 11:15:04**

[Condition ongoing at study entry](#)

| Audit                  | User                             | Time (GMT)           |
|------------------------|----------------------------------|----------------------|
| User entered 'Yes (Y)' | Kaitlin Mason (b) (4)<br>(b) (4) | 20 Nov 2020 17:59:46 |

US3742169

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 26 Nov 2020 11:15:04**

If No, please specify the stop date (dd MMM yyyy)

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| User entered empty. | Kaitlin Mason (b) (4)<br>(b) (4) | 20 Nov 2020 17:59:46 |

US3742169

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 26 Nov 2020 11:15:04**

[Stop date completely unknown](#)

| Audit            | User                             | Time (GMT)           |
|------------------|----------------------------------|----------------------|
| User entered '0' | Kaitlin Mason (b) (4)<br>(b) (4) | 20 Nov 2020 17:59:46 |

US3742169

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 26 Nov 2020 11:15:04**

[Start Month and Year \(derived\)](#)

| Audit                   | User   | Time (GMT)           |
|-------------------------|--------|----------------------|
| User entered 'Jan 2020' | System | 20 Nov 2020 17:59:46 |

US3742169

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 26 Nov 2020 11:15:04**

[Start Year \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '2020' | System | 20 Nov 2020 17:59:46 |



US3742169

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 26 Nov 2020 11:15:04**

[Stop Month and Year \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 20 Nov 2020 17:59:46 |

US3742169

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 26 Nov 2020 11:15:04**

[Stop Year \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 20 Nov 2020 17:59:46 |

US3742169

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:04

[Were vital signs assessed?](#)

| Audit                  | User                           | Time (GMT)           |
|------------------------|--------------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)               | 01 Oct 2020 20:21:34 |
| User entered 'Yes (Y)' | Hassan Haji (b) (4)<br>(b) (4) | 31 Aug 2020 17:42:44 |

US3742169

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:04

Date of assessment (*dd MMM yyyy*)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 01 Oct 2020 20:21:34 |
| User entered '31 Aug 2020' | Hassan Haji (b) (4)<br>(b) (4) | 31 Aug 2020 17:42:44 |

US3742169

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 11:15:04**

[Time of assessment \(00:00-23:59\)](#)

| Audit                | User                           | Time (GMT)           |
|----------------------|--------------------------------|----------------------|
| DataPoint Verified.  | (b) (4), (b) (6)               | 01 Oct 2020 20:21:34 |
| User entered '08:22' | Hassan Haji (b) (4)<br>(b) (4) | 31 Aug 2020 17:42:44 |

US3742169

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 11:15:04**

[Vital Signs Date and Time \(derived\)](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '31 Aug 2020 08:22' | System | 31 Aug 2020 17:42:44 |

US3742169

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:04

[Height \(xxx.x\)](#)

| Audit                     | User                | Time (GMT)           |
|---------------------------|---------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)    | 01 Oct 2020 20:21:34 |
| User entered '65.8' in    | Hassan Haji (b) (4) | 31 Aug 2020 17:42:44 |
| DataPoint set to visible. | (b) (4)<br>System   | 31 Aug 2020 13:36:49 |

US3742169

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:04

[Weight \(xxx.x\)](#)

| Audit                     | User                | Time (GMT)           |
|---------------------------|---------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)    | 01 Oct 2020 20:21:34 |
| User entered '189.5' lb   | Hassan Haji (b) (4) | 31 Aug 2020 17:42:44 |
| DataPoint set to visible. | (b) (4)<br>System   | 31 Aug 2020 13:36:49 |



US3742169

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:04

BMI (xxx.x)

| Audit                     | User   | Time (GMT)           |
|---------------------------|--------|----------------------|
| User entered '30.83666'   | System | 31 Aug 2020 17:42:44 |
| DataPoint set to visible. | System | 31 Aug 2020 13:36:49 |

US3742169

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:04

[BMI units](#)

| Audit                     | User   | Time (GMT)           |
|---------------------------|--------|----------------------|
| User entered 'kg/m2'      | System | 31 Aug 2020 17:42:44 |
| DataPoint set to visible. | System | 31 Aug 2020 13:36:49 |

US3742169

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:04

Temperature (xxx.x)

| Audit                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | User                           | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------|----------------------|
| DataPoint Verified.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | (b) (4), (b) (6)               | 01 Oct 2020 20:21:34 |
| User closed query 'Per CDM: To avoid duplication of data, the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dosed on the same day; screening vitals should only capture the response to "Were vital signs assessed", date, time, height and weight. All other enterable data fields should be recorded as ND. Vital Signs-Dosing should be completed except for the HT and WT, these should be recorded as ND. Please update accordingly. ' (Site from DM).                           | (b) (4), (b) (6)               | 25 Sep 2020 11:48:57 |
| Query 'Per CDM: To avoid duplication of data, the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dosed on the same day; screening vitals should only capture the response to "Were vital signs assessed", date, time, height and weight. All other enterable data fields should be recorded as ND. Vital Signs-Dosing should be completed except for the HT and WT, these should be recorded as ND. Please update accordingly. ' answered with 'DATA HAS BEEN REMOVED' (Site from DM). | (b) (4), (b) (6)               | 24 Sep 2020 13:36:41 |
| User entered missing code ND - Not Done; reason for change Data Entry Error                                                                                                                                                                                                                                                                                                                                                                                                                                            | (b) (4), (b) (6)               | 24 Sep 2020 13:36:33 |
| User opened query 'Per CDM: To avoid duplication of data, the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dosed on the same day; screening vitals should only capture the response to "Were vital signs assessed", date, time, height and weight. All other enterable data fields should be recorded as ND. Vital Signs-Dosing should be completed except for the HT and WT, these should be recorded as ND. Please update accordingly. ' (Site from DM).                           | (b) (4), (b) (6)               | 21 Sep 2020 16:32:31 |
| User entered '097.9' F                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | Hassan Haji (b) (4)<br>(b) (4) | 31 Aug 2020 17:42:44 |

US3742169

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:04

[Route of measurement](#)

| Audit                                                  | User                           | Time (GMT)           |
|--------------------------------------------------------|--------------------------------|----------------------|
| DataPoint Verified.                                    | (b) (4), (b) (6)               | 01 Oct 2020 20:21:34 |
| User entered empty; reason for change Data Entry Error | (b) (4), (b) (6)               | 24 Sep 2020 13:36:33 |
| User entered 'Oral (Oral)'                             | Hassan Haji (b) (4)<br>(b) (4) | 31 Aug 2020 17:42:44 |

US3742169

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:04

[If Other, specify](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 01 Oct 2020 20:21:34 |
| User entered empty. | Hassan Haji (b) (4)<br>(b) (4) | 31 Aug 2020 17:42:44 |

US3742169

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:04

[Pulse \(xxx\)](#)

| Audit                                                                          | User                           | Time (GMT)           |
|--------------------------------------------------------------------------------|--------------------------------|----------------------|
| DataPoint Verified.                                                            | (b) (4), (b) (6)               | 01 Oct 2020 20:21:34 |
| User entered missing code ND - Not Done; reason for<br>change Data Entry Error | (b) (4), (b) (6)               | 24 Sep 2020 13:36:33 |
| User entered '061'                                                             | Hassan Haji (b) (4)<br>(b) (4) | 31 Aug 2020 17:42:44 |

US3742169

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 11:15:04**

[Pulse units](#)

| Audit              | User   | Time (GMT)           |
|--------------------|--------|----------------------|
| User entered 'bpm' | System | 31 Aug 2020 17:42:44 |

US3742169

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:04

[Respiratory Rate \(xxx\)](#)

| Audit                                                                          | User                           | Time (GMT)           |
|--------------------------------------------------------------------------------|--------------------------------|----------------------|
| DataPoint Verified.                                                            | (b) (4), (b) (6)               | 01 Oct 2020 20:21:34 |
| User entered missing code ND - Not Done; reason for<br>change Data Entry Error | (b) (4), (b) (6)               | 24 Sep 2020 13:36:33 |
| User entered '16'                                                              | Hassan Haji (b) (4)<br>(b) (4) | 31 Aug 2020 17:42:44 |



US3742169

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 11:15:04**

[Respiratory Rate units](#)

| Audit                      | User   | Time (GMT)           |
|----------------------------|--------|----------------------|
| User entered 'breaths/min' | System | 31 Aug 2020 17:42:44 |

US3742169

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:04

[Systolic Blood Pressure \(xxx\)](#)

| Audit                                                                       | User                           | Time (GMT)           |
|-----------------------------------------------------------------------------|--------------------------------|----------------------|
| DataPoint Verified.                                                         | (b) (4), (b) (6)               | 01 Oct 2020 20:21:34 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | (b) (4), (b) (6)               | 24 Sep 2020 13:36:33 |
| User entered '120'                                                          | Hassan Haji (b) (4)<br>(b) (4) | 31 Aug 2020 17:42:44 |

US3742169

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 11:15:04**

[Systolic Blood Pressure units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 31 Aug 2020 17:42:44 |

US3742169

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:04

[Diastolic Blood Pressure \(xxx\)](#)

| Audit                                                                       | User                           | Time (GMT)           |
|-----------------------------------------------------------------------------|--------------------------------|----------------------|
| DataPoint Verified.                                                         | (b) (4), (b) (6)               | 01 Oct 2020 20:21:34 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | (b) (4), (b) (6)               | 24 Sep 2020 13:36:33 |
| User entered '080'                                                          | Hassan Haji (b) (4)<br>(b) (4) | 31 Aug 2020 17:42:44 |

US3742169

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 11:15:04**

[Diastolic Blood Pressure units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 31 Aug 2020 17:42:44 |

US3742169

**Folder: Screening**

**Form: Physical Examination**

**Generated On: 26 Nov 2020 11:15:04**

[Was the physical examination performed?](#)

| Audit                  | User                           | Time (GMT)           |
|------------------------|--------------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)               | 01 Oct 2020 20:21:42 |
| User entered 'Yes (Y)' | Hassan Haji (b) (4)<br>(b) (4) | 31 Aug 2020 17:42:51 |

US3742169

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 11:15:04

Date of examination (*dd MMM yyyy*)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 01 Oct 2020 20:21:42 |
| User entered '31 Aug 2020' | Hassan Haji (b) (4)<br>(b) (4) | 31 Aug 2020 17:42:51 |

US3742169

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:15:04

**Healthcare workers** (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

| Audit                 | User                           | Time (GMT)           |
|-----------------------|--------------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)               | 01 Oct 2020 20:21:49 |
| User entered 'No (N)' | Hassan Haji (b) (4)<br>(b) (4) | 31 Aug 2020 13:37:31 |



US3742169

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:15:04

**Emergency Response** (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

| Audit                 | User                           | Time (GMT)           |
|-----------------------|--------------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)               | 01 Oct 2020 20:21:49 |
| User entered 'No (N)' | Hassan Haji (b) (4)<br>(b) (4) | 31 Aug 2020 13:37:31 |

US3742169

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:15:04

**Retail or Restaurant Operations**, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

| Audit                 | User                           | Time (GMT)           |
|-----------------------|--------------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)               | 01 Oct 2020 20:21:49 |
| User entered 'No (N)' | Hassan Haji (b) (4)<br>(b) (4) | 31 Aug 2020 13:37:31 |

US3742169

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:15:04

**Manufacturing & Production Operations** with inherent overcrowding (e.g., factory workers, meat/food processing plants)

| Audit                 | User                           | Time (GMT)           |
|-----------------------|--------------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)               | 01 Oct 2020 20:21:49 |
| User entered 'No (N)' | Hassan Haji (b) (4)<br>(b) (4) | 31 Aug 2020 13:37:31 |

US3742169

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:15:04

[Warehouse shipping and fulfillment centers](#) and jobs (e.g., Amazon facilities)

| Audit                 | User                           | Time (GMT)           |
|-----------------------|--------------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)               | 01 Oct 2020 20:21:49 |
| User entered 'No (N)' | Hassan Haji (b) (4)<br>(b) (4) | 31 Aug 2020 13:37:31 |

US3742169

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:15:04

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

| Audit                 | User                           | Time (GMT)           |
|-----------------------|--------------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)               | 01 Oct 2020 20:21:49 |
| User entered 'No (N)' | Hassan Haji (b) (4)<br>(b) (4) | 31 Aug 2020 13:37:31 |

US3742169

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:15:04

**Border Protection and Military Personnel** (e.g., TSA, custom and border protection agents, military personnel not social distancing)

| Audit                 | User                           | Time (GMT)           |
|-----------------------|--------------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)               | 01 Oct 2020 20:21:49 |
| User entered 'No (N)' | Hassan Haji (b) (4)<br>(b) (4) | 31 Aug 2020 13:37:31 |

US3742169

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:15:04

**Personal Care and in-home services** (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

| Audit                 | User                           | Time (GMT)           |
|-----------------------|--------------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)               | 01 Oct 2020 20:21:49 |
| User entered 'No (N)' | Hassan Haji (b) (4)<br>(b) (4) | 31 Aug 2020 13:37:31 |

US3742169

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:15:04

**Hospitality and Tourism Workers** (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

| Audit                 | User                           | Time (GMT)           |
|-----------------------|--------------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)               | 01 Oct 2020 20:21:49 |
| User entered 'No (N)' | Hassan Haji (b) (4)<br>(b) (4) | 31 Aug 2020 13:37:31 |



US3742169

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:15:04

**Pastoral, Social or Public Health Workers** requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

| Audit                 | User                           | Time (GMT)           |
|-----------------------|--------------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)               | 01 Oct 2020 20:21:49 |
| User entered 'No (N)' | Hassan Haji (b) (4)<br>(b) (4) | 31 Aug 2020 13:37:31 |

US3742169

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:15:04

**Educators and Students** (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

| Audit                  | User                           | Time (GMT)           |
|------------------------|--------------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)               | 01 Oct 2020 20:21:49 |
| User entered 'Yes (Y)' | Hassan Haji (b) (4)<br>(b) (4) | 31 Aug 2020 13:37:31 |

US3742169

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:15:04

[Other](#)

| Audit                 | User                           | Time (GMT)           |
|-----------------------|--------------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)               | 01 Oct 2020 20:21:49 |
| User entered 'No (N)' | Hassan Haji (b) (4)<br>(b) (4) | 31 Aug 2020 13:37:31 |

US3742169

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:15:04

[Specify](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 01 Oct 2020 20:21:49 |
| User entered empty. | Hassan Haji (b) (4)<br>(b) (4) | 31 Aug 2020 13:37:31 |

US3742169

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:15:04

No Risk Identified

| Audit            | User                           | Time (GMT)           |
|------------------|--------------------------------|----------------------|
| User entered '1' | Hassan Haji (b) (4)<br>(b) (4) | 31 Aug 2020 13:37:31 |

US3742169

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:15:04

[Resides in Nursing Home or Assisted Living Facility](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 01 Oct 2020 20:21:49 |
| User entered '0'    | Hassan Haji (b) (4)<br>(b) (4) | 31 Aug 2020 13:37:31 |

US3742169

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:15:04

**Resides in Multi-family dwelling** (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 01 Oct 2020 20:21:49 |
| User entered '0'    | Hassan Haji (b) (4)<br>(b) (4) | 31 Aug 2020 13:37:31 |

US3742169

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:15:04

**Resides in high density housing** (e.g., high rise apartments with shared entrances or elevators)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 01 Oct 2020 20:21:49 |
| User entered '0'    | Hassan Haji (b) (4)<br>(b) (4) | 31 Aug 2020 13:37:31 |



US3742169

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:15:04

**Resides in low density, multi-family setting without** (e.g., apartments complex without shared entrances or elevators, duplexes)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 01 Oct 2020 20:21:49 |
| User entered '0'    | Hassan Haji (b) (4)<br>(b) (4) | 31 Aug 2020 13:37:31 |

US3742169

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:15:04

[Resides in a single family home](#) (i.e., detached housing)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 01 Oct 2020 20:21:49 |
| User entered '0'    | Hassan Haji (b) (4)<br>(b) (4) | 31 Aug 2020 13:37:31 |

US3742169

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:15:04

[Other](#)

| Audit            | User                           | Time (GMT)           |
|------------------|--------------------------------|----------------------|
| User entered '0' | Hassan Haji (b) (4)<br>(b) (4) | 31 Aug 2020 13:37:31 |

US3742169

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:15:04

[Specify](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 01 Oct 2020 20:21:49 |
| User entered empty. | Hassan Haji (b) (4)<br>(b) (4) | 31 Aug 2020 13:37:31 |

US3742169

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:15:04

[Was this visit performed?](#)

| Audit                  | User                           | Time (GMT)           |
|------------------------|--------------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)               | 01 Oct 2020 20:22:13 |
| User entered 'Yes (Y)' | Hassan Haji (b) (4)<br>(b) (4) | 31 Aug 2020 17:43:14 |

US3742169

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:15:04

[Visit date \(dd MMM yyyy\)](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 01 Oct 2020 20:22:13 |
| User entered '31 Aug 2020' | Hassan Haji (b) (4)<br>(b) (4) | 31 Aug 2020 17:43:14 |

US3742169

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:15:04

[Was visit performed at the participant's home or at the clinic?](#)

| Audit                          | User                           | Time (GMT)           |
|--------------------------------|--------------------------------|----------------------|
| DataPoint Verified.            | (b) (4), (b) (6)               | 01 Oct 2020 20:22:13 |
| User entered 'Clinic (Clinic)' | Hassan Haji (b) (4)<br>(b) (4) | 31 Aug 2020 17:43:14 |

**US3742169**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 26 Nov 2020 11:15:04**

[Folder OID](#)

| Audit                 | User   | Time (GMT)           |
|-----------------------|--------|----------------------|
| User entered 'VISIT1' | System | 31 Aug 2020 17:43:14 |



US3742169

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:15:04

What was the date of randomization? (dd MMM yyyy)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                 | 01 Oct 2020 20:22:18 |
| User entered '31 AUG 2020' | RWS_ENDPOINT<br>ENDPOINT (b) (4) | 31 Aug 2020 12:59:31 |

US3742169

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:15:04

[What was the participant's randomization number?](#)

| Audit                 | User                             | Time (GMT)           |
|-----------------------|----------------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)                 | 01 Oct 2020 20:22:18 |
| User entered '145292' | RWS_ENDPOINT<br>ENDPOINT (b) (4) | 31 Aug 2020 12:59:31 |

US3742169

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:15:04

[In what Cohort was the participant enrolled?](#)

| Audit                                             | User                             | Time (GMT)           |
|---------------------------------------------------|----------------------------------|----------------------|
| DataPoint Verified.                               | (b) (4), (b) (6)                 | 01 Oct 2020 20:22:18 |
| User entered '>=18 and <65 years and at risk (2)' | RWS_ENDPOINT<br>ENDPOINT (b) (4) | 31 Aug 2020 12:59:31 |

US3742169

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:15:04

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

| Audit                  | User                           | Time (GMT)           |
|------------------------|--------------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)               | 01 Oct 2020 20:22:18 |
| User entered 'Yes (Y)' | Hassan Haji (b) (4)<br>(b) (4) | 31 Aug 2020 17:43:45 |

US3742169

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:15:04

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

| Audit                 | User                           | Time (GMT)           |
|-----------------------|--------------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)               | 01 Oct 2020 20:22:18 |
| User entered 'No (N)' | Hassan Haji (b) (4)<br>(b) (4) | 31 Aug 2020 17:43:45 |

US3742169

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:15:04

Severe obesity (body mass index > or = 40kg/m2

| Audit                 | User                           | Time (GMT)           |
|-----------------------|--------------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)               | 01 Oct 2020 20:22:18 |
| User entered 'No (N)' | Hassan Haji (b) (4)<br>(b) (4) | 31 Aug 2020 17:43:45 |

US3742169

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:15:04

Diabetes (Type I, Type 2, or gestational)

| Audit                 | User                           | Time (GMT)           |
|-----------------------|--------------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)               | 01 Oct 2020 20:22:18 |
| User entered 'No (N)' | Hassan Haji (b) (4)<br>(b) (4) | 31 Aug 2020 17:43:45 |

US3742169

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:15:04

[Liver Disease](#)

| Audit                 | User                           | Time (GMT)           |
|-----------------------|--------------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)               | 01 Oct 2020 20:22:18 |
| User entered 'No (N)' | Hassan Haji (b) (4)<br>(b) (4) | 31 Aug 2020 17:43:45 |



US3742169

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:15:04

[Human Immunodeficiency Virus \(HIV\) infection](#)

| Audit                                        | User             | Time (GMT)           |
|----------------------------------------------|------------------|----------------------|
| DataPoint Verified.                          | (b) (4), (b) (6) | 01 Oct 2020 20:22:18 |
| User entered 'No (N)'                        | (b) (4), (b) (6) | 24 Sep 2020 13:37:26 |
| Amendment Manager: DataPoint set to visible. | System           | 19 Sep 2020 08:39:39 |
| Amendment Manager inserted this DataPoint.   | System           | 19 Sep 2020 08:39:38 |

US3742169

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:15:04

Height

| Audit                                                                                                                                                                                                                                                                                             | User                           | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------|----------------------|
| DataPoint Verified.                                                                                                                                                                                                                                                                               | (b) (4), (b) (6)               | 01 Oct 2020 20:23:10 |
| User closed query 'Per CDM: As per CCGs, p 15-16, "ND" must be entered in HT and WT. Please review and reconcile. ' (Site from DM).                                                                                                                                                               | (b) (4), (b) (6)               | 25 Sep 2020 14:27:27 |
| User closed query 'Per CDM: To avoid duplication of data the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dose on the same day; HT and WT should only captured at screening and recorded as ND at Day 1. Please update accordingly' (Site from DM).             | (b) (4), (b) (6)               | 25 Sep 2020 14:27:25 |
| Query 'Per CDM: As per CCGs, p 15-16, "ND" must be entered in HT and WT. Please review and reconcile. ' answered with 'ND HAS BEEN ADDED' (Site from DM).                                                                                                                                         | (b) (4), (b) (6)               | 24 Sep 2020 13:37:10 |
| User entered missing code ND - Not Done; reason for change Data Entry Error                                                                                                                                                                                                                       | (b) (4), (b) (6)               | 24 Sep 2020 13:36:54 |
| User opened query 'Per CDM: As per CCGs, p 15-16, "ND" must be entered in HT and WT. Please review and reconcile. ' (Site from DM).                                                                                                                                                               | (b) (4), (b) (6)               | 23 Sep 2020 13:44:01 |
| Query 'Per CDM: To avoid duplication of data the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dose on the same day; HT and WT should only captured at screening and recorded as ND at Day 1. Please update accordingly' answered with 'UPDATED' (Site from DM). | (b) (4), (b) (6)               | 22 Sep 2020 17:35:03 |
| User entered empty; reason for change Data Entry Error                                                                                                                                                                                                                                            | (b) (4), (b) (6)               | 22 Sep 2020 17:34:57 |
| User opened query 'Per CDM: To avoid duplication of data the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dose on the same day; HT and WT should only captured at screening and recorded as ND at Day 1. Please update accordingly' (Site from DM).             | (b) (4), (b) (6)               | 21 Sep 2020 11:42:27 |
| User entered '65.8' in                                                                                                                                                                                                                                                                            | Hassan Haji (b) (4)<br>(b) (4) | 31 Aug 2020 17:45:55 |

US3742169

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:15:04

Weight

| Audit                                                                                                                                  | User                           | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------|--------------------------------|----------------------|
| DataPoint Verified.                                                                                                                    | (b) (4), (b) (6)               | 01 Oct 2020 20:23:10 |
| User closed query 'Per CDM: Please update Weight with ND.' (Site from DM).                                                             | (b) (4), (b) (6)               | 25 Sep 2020 18:03:06 |
| Query 'Per CDM: Please update Weight with ND.' answered with 'DATA REMOVED AND ND ENTERED TO PREVENT DATA DUPLICATION' (Site from DM). | (b) (4), (b) (6)               | 25 Sep 2020 15:46:30 |
| User entered missing code ND - Not Done; reason for change Data Entry Error                                                            | (b) (4), (b) (6)               | 25 Sep 2020 15:46:07 |
| User opened query 'Per CDM: Please update Weight with ND.' (Site from DM).                                                             | (b) (4), (b) (6)               | 25 Sep 2020 11:54:06 |
| User entered empty; reason for change Data Entry Error                                                                                 | (b) (4), (b) (6)               | 22 Sep 2020 17:34:57 |
| User entered '189.5' lb                                                                                                                | Hassan Haji (b) (4)<br>(b) (4) | 31 Aug 2020 17:45:55 |

US3742169

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:15:04

Height

| Audit                                                                                                                                                                                                                                                                                             | User                           | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------|----------------------|
| DataPoint Verified.                                                                                                                                                                                                                                                                               | (b) (4), (b) (6)               | 01 Oct 2020 20:23:10 |
| User closed query 'Per CDM: As per CCGs, p 15-16, "ND" must be entered in HT and WT. Please review and reconcile. ' (Site from DM).                                                                                                                                                               | (b) (4), (b) (6)               | 25 Sep 2020 14:27:27 |
| User closed query 'Per CDM: To avoid duplication of data the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dose on the same day; HT and WT should only captured at screening and recorded as ND at Day 1. Please update accordingly' (Site from DM).             | (b) (4), (b) (6)               | 25 Sep 2020 14:27:25 |
| Query 'Per CDM: As per CCGs, p 15-16, "ND" must be entered in HT and WT. Please review and reconcile. ' answered with 'ND HAS BEEN ADDED' (Site from DM).                                                                                                                                         | (b) (4), (b) (6)               | 24 Sep 2020 13:37:10 |
| User entered missing code ND - Not Done; reason for change Data Entry Error                                                                                                                                                                                                                       | (b) (4), (b) (6)               | 24 Sep 2020 13:36:54 |
| User opened query 'Per CDM: As per CCGs, p 15-16, "ND" must be entered in HT and WT. Please review and reconcile. ' (Site from DM).                                                                                                                                                               | (b) (4), (b) (6)               | 23 Sep 2020 13:44:01 |
| Query 'Per CDM: To avoid duplication of data the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dose on the same day; HT and WT should only captured at screening and recorded as ND at Day 1. Please update accordingly' answered with 'UPDATED' (Site from DM). | (b) (4), (b) (6)               | 22 Sep 2020 17:35:03 |
| User entered empty; reason for change Data Entry Error                                                                                                                                                                                                                                            | (b) (4), (b) (6)               | 22 Sep 2020 17:34:57 |
| User opened query 'Per CDM: To avoid duplication of data the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dose on the same day; HT and WT should only captured at screening and recorded as ND at Day 1. Please update accordingly' (Site from DM).             | (b) (4), (b) (6)               | 21 Sep 2020 11:42:27 |
| User entered '65.8' in                                                                                                                                                                                                                                                                            | Hassan Haji (b) (4)<br>(b) (4) | 31 Aug 2020 17:45:55 |

US3742169

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:15:04

Weight

| Audit                                                                                                                                  | User                           | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------|--------------------------------|----------------------|
| DataPoint Verified.                                                                                                                    | (b) (4), (b) (6)               | 01 Oct 2020 20:23:10 |
| User closed query 'Per CDM: Please update Weight with ND.' (Site from DM).                                                             | (b) (4), (b) (6)               | 25 Sep 2020 18:03:06 |
| Query 'Per CDM: Please update Weight with ND.' answered with 'DATA REMOVED AND ND ENTERED TO PREVENT DATA DUPLICATION' (Site from DM). | (b) (4), (b) (6)               | 25 Sep 2020 15:46:30 |
| User entered missing code ND - Not Done; reason for change Data Entry Error                                                            | (b) (4), (b) (6)               | 25 Sep 2020 15:46:07 |
| User opened query 'Per CDM: Please update Weight with ND.' (Site from DM).                                                             | (b) (4), (b) (6)               | 25 Sep 2020 11:54:06 |
| User entered empty; reason for change Data Entry Error                                                                                 | (b) (4), (b) (6)               | 22 Sep 2020 17:34:57 |
| User entered '189.5' lb                                                                                                                | Hassan Haji (b) (4)<br>(b) (4) | 31 Aug 2020 17:45:55 |

US3742169

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:15:04

[Timepoint](#)

| Audit                                            | User                           | Time (GMT)           |
|--------------------------------------------------|--------------------------------|----------------------|
| User accepted default value 'Pre-Dose (PREDOSE)' | Hassan Haji (b) (4)<br>(b) (4) | 31 Aug 2020 17:45:55 |

US3742169

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:15:04

[Were vital signs assessed?](#)

| Audit                  | User                           | Time (GMT)           |
|------------------------|--------------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)               | 01 Oct 2020 20:23:10 |
| User entered 'Yes (Y)' | Hassan Haji (b) (4)<br>(b) (4) | 31 Aug 2020 17:45:55 |

US3742169

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:15:04

Date of assessment (*dd MMM yyyy*)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 01 Oct 2020 20:23:10 |
| User entered '31 Aug 2020' | Hassan Haji (b) (4)<br>(b) (4) | 31 Aug 2020 17:45:55 |



US3742169

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:15:04

[Time of assessment \(00:00-23:59\)](#)

| Audit                | User                           | Time (GMT)           |
|----------------------|--------------------------------|----------------------|
| DataPoint Verified.  | (b) (4), (b) (6)               | 01 Oct 2020 20:23:10 |
| User entered '08:22' | Hassan Haji (b) (4)<br>(b) (4) | 31 Aug 2020 17:45:55 |

US3742169

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:15:04

[Vital Signs Date and Time \(derived\)](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '31 Aug 2020 08:22' | System | 31 Aug 2020 17:45:55 |

US3742169

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:15:04

Temperature (xxx.x)

| Audit                  | User                           | Time (GMT)           |
|------------------------|--------------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)               | 01 Oct 2020 20:23:10 |
| User entered '097.9' F | Hassan Haji (b) (4)<br>(b) (4) | 31 Aug 2020 17:45:55 |

US3742169

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:15:04

[Route of measurement](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 01 Oct 2020 20:23:10 |
| User entered 'Oral (Oral)' | Hassan Haji (b) (4)<br>(b) (4) | 31 Aug 2020 17:45:55 |

US3742169

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:15:04

[If Other, specify](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 01 Oct 2020 20:23:10 |
| User entered empty. | Hassan Haji (b) (4)<br>(b) (4) | 31 Aug 2020 17:45:55 |

US3742169

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:15:04

[Pulse \(xxx\)](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 01 Oct 2020 20:23:10 |
| User entered '061'  | Hassan Haji (b) (4)<br>(b) (4) | 31 Aug 2020 17:45:55 |

US3742169

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:15:04

[Pulse units](#)

| Audit              | User   | Time (GMT)           |
|--------------------|--------|----------------------|
| User entered 'bpm' | System | 31 Aug 2020 17:45:55 |

US3742169

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:15:04

[Respiratory Rate \(xxx\)](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 01 Oct 2020 20:23:10 |
| User entered '16'   | Hassan Haji (b) (4)<br>(b) (4) | 31 Aug 2020 17:45:55 |



US3742169

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:15:04

[Respiratory Rate units](#)

| Audit                      | User   | Time (GMT)           |
|----------------------------|--------|----------------------|
| User entered 'breaths/min' | System | 31 Aug 2020 17:45:55 |

US3742169

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:15:04

Systolic Blood Pressure (xxx)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 01 Oct 2020 20:23:10 |
| User entered '120'  | Hassan Haji (b) (4)<br>(b) (4) | 31 Aug 2020 17:45:55 |

US3742169

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:15:04

[Systolic Blood Pressure units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 31 Aug 2020 17:45:55 |

US3742169

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:15:04

Diastolic Blood Pressure (xxx)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 01 Oct 2020 20:23:10 |
| User entered '080'  | Hassan Haji (b) (4)<br>(b) (4) | 31 Aug 2020 17:45:55 |

US3742169

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:15:04

[Diastolic Blood Pressure units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 31 Aug 2020 17:45:55 |

US3742169

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:15:04

Height

| Audit                                                                                                                                                                                                                                                                                             | User                           | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------|----------------------|
| DataPoint Verified.                                                                                                                                                                                                                                                                               | (b) (4), (b) (6)               | 01 Oct 2020 20:23:10 |
| User closed query 'Per CDM: As per CCGs, p 15-16, "ND" must be entered in HT and WT. Please review and reconcile. ' (Site from DM).                                                                                                                                                               | (b) (4), (b) (6)               | 25 Sep 2020 14:27:27 |
| User closed query 'Per CDM: To avoid duplication of data the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dose on the same day; HT and WT should only captured at screening and recorded as ND at Day 1. Please update accordingly' (Site from DM).             | (b) (4), (b) (6)               | 25 Sep 2020 14:27:25 |
| Query 'Per CDM: As per CCGs, p 15-16, "ND" must be entered in HT and WT. Please review and reconcile. ' answered with 'ND HAS BEEN ADDED' (Site from DM).                                                                                                                                         | (b) (4), (b) (6)               | 24 Sep 2020 13:37:10 |
| User entered missing code ND - Not Done; reason for change Data Entry Error                                                                                                                                                                                                                       | (b) (4), (b) (6)               | 24 Sep 2020 13:36:54 |
| User opened query 'Per CDM: As per CCGs, p 15-16, "ND" must be entered in HT and WT. Please review and reconcile. ' (Site from DM).                                                                                                                                                               | (b) (4), (b) (6)               | 23 Sep 2020 13:44:01 |
| Query 'Per CDM: To avoid duplication of data the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dose on the same day; HT and WT should only captured at screening and recorded as ND at Day 1. Please update accordingly' answered with 'UPDATED' (Site from DM). | (b) (4), (b) (6)               | 22 Sep 2020 17:35:03 |
| User entered empty; reason for change Data Entry Error                                                                                                                                                                                                                                            | (b) (4), (b) (6)               | 22 Sep 2020 17:34:57 |
| User opened query 'Per CDM: To avoid duplication of data the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dose on the same day; HT and WT should only captured at screening and recorded as ND at Day 1. Please update accordingly' (Site from DM).             | (b) (4), (b) (6)               | 21 Sep 2020 11:42:27 |
| User entered '65.8' in                                                                                                                                                                                                                                                                            | Hassan Haji (b) (4)<br>(b) (4) | 31 Aug 2020 17:45:55 |

US3742169

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:15:04

Weight

| Audit                                                                                                                                  | User                           | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------|--------------------------------|----------------------|
| DataPoint Verified.                                                                                                                    | (b) (4), (b) (6)               | 01 Oct 2020 20:23:10 |
| User closed query 'Per CDM: Please update Weight with ND.' (Site from DM).                                                             | (b) (4), (b) (6)               | 25 Sep 2020 18:03:06 |
| Query 'Per CDM: Please update Weight with ND.' answered with 'DATA REMOVED AND ND ENTERED TO PREVENT DATA DUPLICATION' (Site from DM). | (b) (4), (b) (6)               | 25 Sep 2020 15:46:30 |
| User entered missing code ND - Not Done; reason for change Data Entry Error                                                            | (b) (4), (b) (6)               | 25 Sep 2020 15:46:07 |
| User opened query 'Per CDM: Please update Weight with ND.' (Site from DM).                                                             | (b) (4), (b) (6)               | 25 Sep 2020 11:54:06 |
| User entered empty; reason for change Data Entry Error                                                                                 | (b) (4), (b) (6)               | 22 Sep 2020 17:34:57 |
| User entered '189.5' lb                                                                                                                | Hassan Haji (b) (4)<br>(b) (4) | 31 Aug 2020 17:45:55 |

US3742169

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:15:04

[Timepoint](#)

| Audit                                              | User                           | Time (GMT)           |
|----------------------------------------------------|--------------------------------|----------------------|
| User accepted default value 'Post-Dose (POSTDOSE)' | Hassan Haji (b) (4)<br>(b) (4) | 31 Aug 2020 17:45:55 |



US3742169

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:15:04

[Were vital signs assessed?](#)

| Audit                  | User                           | Time (GMT)           |
|------------------------|--------------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)               | 01 Oct 2020 20:23:10 |
| User entered 'Yes (Y)' | Hassan Haji (b) (4)<br>(b) (4) | 31 Aug 2020 17:45:55 |

US3742169

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:15:04

Date of assessment (*dd MMM yyyy*)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 01 Oct 2020 20:23:10 |
| User entered '31 Aug 2020' | Hassan Haji (b) (4)<br>(b) (4) | 31 Aug 2020 17:45:55 |

US3742169

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:15:04

[Time of assessment \(00:00-23:59\)](#)

| Audit                | User                           | Time (GMT)           |
|----------------------|--------------------------------|----------------------|
| DataPoint Verified.  | (b) (4), (b) (6)               | 01 Oct 2020 20:23:10 |
| User entered '10:07' | Hassan Haji (b) (4)<br>(b) (4) | 31 Aug 2020 17:45:55 |

US3742169

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:15:04

[Vital Signs Date and Time \(derived\)](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '31 Aug 2020 10:07' | System | 31 Aug 2020 17:45:55 |

US3742169

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:15:04

Temperature (xxx.x)

| Audit                 | User                           | Time (GMT)           |
|-----------------------|--------------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)               | 01 Oct 2020 20:23:10 |
| User entered '97.8' F | Hassan Haji (b) (4)<br>(b) (4) | 31 Aug 2020 17:45:55 |

US3742169

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:15:04

[Route of measurement](#)

| Audit                        | User                           | Time (GMT)           |
|------------------------------|--------------------------------|----------------------|
| DataPoint Verified.          | (b) (4), (b) (6)               | 01 Oct 2020 20:23:10 |
| User entered 'Other (Other)' | Hassan Haji (b) (4)<br>(b) (4) | 31 Aug 2020 17:45:55 |

US3742169

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:15:04

[If Other, specify](#)

| Audit                   | User                           | Time (GMT)           |
|-------------------------|--------------------------------|----------------------|
| DataPoint Verified.     | (b) (4), (b) (6)               | 01 Oct 2020 20:23:10 |
| User entered 'forehead' | Hassan Haji (b) (4)<br>(b) (4) | 31 Aug 2020 17:45:55 |

US3742169

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:15:04

[Pulse \(xxx\)](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 01 Oct 2020 20:23:10 |
| User entered '066'  | Hassan Haji (b) (4)<br>(b) (4) | 31 Aug 2020 17:45:55 |



US3742169

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:15:04

[Pulse units](#)

| Audit              | User   | Time (GMT)           |
|--------------------|--------|----------------------|
| User entered 'bpm' | System | 31 Aug 2020 17:45:55 |

US3742169

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:15:04

[Respiratory Rate \(xxx\)](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 01 Oct 2020 20:23:10 |
| User entered '20'   | Hassan Haji (b) (4)<br>(b) (4) | 31 Aug 2020 17:45:55 |

US3742169

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:15:04

[Respiratory Rate units](#)

| Audit                      | User   | Time (GMT)           |
|----------------------------|--------|----------------------|
| User entered 'breaths/min' | System | 31 Aug 2020 17:45:55 |

US3742169

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:15:04

Systolic Blood Pressure (xxx)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 01 Oct 2020 20:23:10 |
| User entered '122'  | Hassan Haji (b) (4)<br>(b) (4) | 31 Aug 2020 17:45:55 |

US3742169

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:15:04

[Systolic Blood Pressure units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 31 Aug 2020 17:45:55 |

US3742169

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:15:04

Diastolic Blood Pressure (xxx)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 01 Oct 2020 20:23:10 |
| User entered '80'   | Hassan Haji (b) (4)<br>(b) (4) | 31 Aug 2020 17:45:55 |

US3742169

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:15:04

[Diastolic Blood Pressure units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 31 Aug 2020 17:45:55 |

US3742169

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 11:15:04

Was the physical examination performed?

| Audit                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | User                           | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------|----------------------|
| DataPoint Verified.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | (b) (4), (b) (6)               | 01 Oct 2020 20:23:18 |
| User closed query 'Per CDM: To avoid duplication of data, the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dose on the same day then completion of the PE form is only required to be completed using the PE form located in the screening folder. Completion of the PE form within the Visit 1 Day 1 folder should be left blank except for the response to "Was the physical examination performed?" This should be "No". Please update accordingly.' (Site from DM).                              | (b) (4), (b) (6)               | 23 Sep 2020 13:42:31 |
| Query 'Per CDM: To avoid duplication of data, the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dose on the same day then completion of the PE form is only required to be completed using the PE form located in the screening folder. Completion of the PE form within the Visit 1 Day 1 folder should be left blank except for the response to "Was the physical examination performed?" This should be "No". Please update accordingly.' answered with 'ENTERED IN ERROR UPDATED' (Site from DM). | (b) (4), (b) (6)               | 21 Sep 2020 17:17:09 |
| User entered 'No (N)' reason for change: Data Entry Error                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | (b) (4), (b) (6)               | 21 Sep 2020 17:17:01 |
| User opened query 'Per CDM: To avoid duplication of data, the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dose on the same day then completion of the PE form is only required to be completed using the PE form located in the screening folder. Completion of the PE form within the Visit 1 Day 1 folder should be left blank except for the response to "Was the physical examination performed?" This should be "No". Please update accordingly.' (Site from DM).                              | (b) (4), (b) (6)               | 21 Sep 2020 16:32:20 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | Hassan Haji (b) (4)<br>(b) (4) | 31 Aug 2020 17:46:11 |



US3742169

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 11:15:04

Date of examination (dd MMM yyyy)

| Audit                                                  | User                           | Time (GMT)           |
|--------------------------------------------------------|--------------------------------|----------------------|
| DataPoint Verified.                                    | (b) (4), (b) (6)               | 01 Oct 2020 20:23:18 |
| User entered empty; reason for change Data Entry Error | (b) (4), (b) (6)               | 21 Sep 2020 17:17:01 |
| User entered '31 Aug 2020'                             | Hassan Haji (b) (4)<br>(b) (4) | 31 Aug 2020 17:46:11 |

US3742169

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:15:04

[Was study treatment given?](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 01 Oct 2020 20:23:35 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 31 Aug 2020 14:08:19 |

US3742169

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:15:04

[If No, reason not given](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 20:23:35 |
| User entered empty. | (b) (4), (b) (6) | 31 Aug 2020 14:08:19 |

US3742169

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:15:04

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 20:23:35 |
| User entered empty. | (b) (4), (b) (6) | 31 Aug 2020 14:08:19 |

US3742169

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:15:04

[What was the study treatment?](#)

| Audit                               | User   | Time (GMT)           |
|-------------------------------------|--------|----------------------|
| User entered 'MRNA-1273 OR PLACEBO' | System | 31 Aug 2020 14:08:19 |

US3742169

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:15:04

[What was the treatment date? \(dd MMM yyyy\)](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 01 Oct 2020 20:23:35 |
| User entered '31 Aug 2020' | (b) (4), (b) (6) | 31 Aug 2020 14:08:19 |

US3742169

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:15:04

[What was the treatment time? \(00:00-23:59\)](#)

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| DataPoint Verified.  | (b) (4), (b) (6) | 01 Oct 2020 20:23:35 |
| User entered '09:33' | (b) (4), (b) (6) | 31 Aug 2020 14:08:19 |

US3742169

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:15:04

[Treatment Date and Time \(derived\)](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '31 Aug 2020 09:33' | System | 31 Aug 2020 14:08:19 |



US3742169

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:15:04

[Which arm was used to give treatment?](#)

| Audit                                | User             | Time (GMT)           |
|--------------------------------------|------------------|----------------------|
| DataPoint Verified.                  | (b) (4), (b) (6) | 01 Oct 2020 20:23:35 |
| User entered 'Right Arm (RIGHT ARM)' | (b) (4), (b) (6) | 31 Aug 2020 14:08:19 |

US3742169

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:15:04

[What was the frequency of the study treatment dosing?](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 20:23:35 |
| User entered 'ONCE' | System           | 31 Aug 2020 14:08:19 |

US3742169

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:15:04

[What was the route of administration for the study treatment?](#)

| Audit                        | User   | Time (GMT)           |
|------------------------------|--------|----------------------|
| User entered 'INTRAMUSCULAR' | System | 31 Aug 2020 14:08:19 |

US3742169

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:15:04

[Was the sample collected?](#)

| Audit                  | User                           | Time (GMT)           |
|------------------------|--------------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)               | 01 Oct 2020 20:23:44 |
| User entered 'Yes (Y)' | Hassan Haji (b) (4)<br>(b) (4) | 31 Aug 2020 13:38:12 |

US3742169

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:15:04

Collection date (dd MMM yyyy)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 01 Oct 2020 20:23:44 |
| User entered '31 Aug 2020' | Hassan Haji (b) (4)<br>(b) (4) | 31 Aug 2020 13:38:12 |

US3742169

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:15:04

Collection time (00:00-23:59)

| Audit                | User                           | Time (GMT)           |
|----------------------|--------------------------------|----------------------|
| DataPoint Verified.  | (b) (4), (b) (6)               | 01 Oct 2020 20:23:44 |
| User entered '08:33' | Hassan Haji (b) (4)<br>(b) (4) | 31 Aug 2020 13:38:12 |

US3742169

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:15:04

[Collection date and time \(derived\)](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '31 Aug 2020 08:33' | System | 31 Aug 2020 13:38:12 |

US3742169

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 11:15:04

Collection date (*dd MMM yyyy*)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 01 Oct 2020 20:24:01 |
| User entered '31 Aug 2020' | Hassan Haji (b) (4)<br>(b) (4) | 31 Aug 2020 13:38:32 |



US3742169

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:15:04

[Lab Test](#)

| Audit                                                        | User                           | Time (GMT)           |
|--------------------------------------------------------------|--------------------------------|----------------------|
| User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)' | Hassan Haji (b) (4)<br>(b) (4) | 31 Aug 2020 13:38:32 |

US3742169

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:15:04

[Was the sample collected?](#)

| Audit                  | User                           | Time (GMT)           |
|------------------------|--------------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)               | 01 Oct 2020 20:24:01 |
| User entered 'Yes (Y)' | Hassan Haji (b) (4)<br>(b) (4) | 31 Aug 2020 13:38:32 |

US3742169

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:15:04

Collection time (00:00 - 23:59)

| Audit                | User                           | Time (GMT)           |
|----------------------|--------------------------------|----------------------|
| DataPoint Verified.  | (b) (4), (b) (6)               | 01 Oct 2020 20:24:01 |
| User entered '08:29' | Hassan Haji (b) (4)<br>(b) (4) | 31 Aug 2020 13:38:32 |

US3742169

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 26 Nov 2020 11:15:04**

[Collection date and time \(derived\)](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '31 Aug 2020 08:29' | System | 31 Aug 2020 13:38:32 |

US3742169

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:15:04

[Lab Test](#)

| Audit                                                        | User                           | Time (GMT)           |
|--------------------------------------------------------------|--------------------------------|----------------------|
| User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)' | Hassan Haji (b) (4)<br>(b) (4) | 31 Aug 2020 13:38:32 |

US3742169

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:15:04

[Was the sample collected?](#)

| Audit                 | User                           | Time (GMT)           |
|-----------------------|--------------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)               | 01 Oct 2020 20:24:01 |
| User entered 'No (N)' | Hassan Haji (b) (4)<br>(b) (4) | 31 Aug 2020 13:38:32 |

US3742169

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:15:04

Collection time (00:00 - 23:59)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 01 Oct 2020 20:24:01 |
| User entered empty. | Hassan Haji (b) (4)<br>(b) (4) | 31 Aug 2020 13:38:32 |

**US3742169**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 26 Nov 2020 11:15:04**

[Collection date and time \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 31 Aug 2020 13:38:32 |



US3742169

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 11:15:04

[Is the participant continuing to the next visit?](#)

| Audit                  | User                           | Time (GMT)           |
|------------------------|--------------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)               | 01 Oct 2020 20:24:13 |
| User entered 'Yes (Y)' | Hassan Haji (b) (4)<br>(b) (4) | 31 Aug 2020 17:46:25 |

US3742169

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 11:15:04

[Continuing Flag](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 31 Aug 2020 17:46:25 |

US3742169

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 26 Nov 2020 11:15:04

**TIMEPOINT**

| Audit                                                                | User   | Time (GMT)           |
|----------------------------------------------------------------------|--------|----------------------|
| Data entry locked.                                                   | System | 31 Aug 2020 14:08:19 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 31 Aug 2020 14:08:19 |

US3742169

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 26 Nov 2020 11:15:04

Was **TEMPERATURE** taken?

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-08-31T10:17:53', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'c3ce0460-9012-4407-9a5e-a695ec2f839c' | System | 31 Aug 2020 14:18:12 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                     | System | 31 Aug 2020 14:18:12 |

US3742169

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 26 Nov 2020 11:15:04

Please record your **TEMPERATURE** in °F

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-08-31T10:18:00', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'c3ce0460-9012-4407-9a5e-a695ec2f839c' | System | 31 Aug 2020 14:18:12 |
| User entered '97.8'                                                                                                                                                                                                                        | System | 31 Aug 2020 14:18:12 |

US3742169

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 26 Nov 2020 11:15:04

Was any **MEDICATION TAKEN** today for pain or fever?

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-08-31T10:18:05', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'c3ce0460-9012-4407-9a5e-a695ec2f839c' | System | 31 Aug 2020 14:18:12 |
| User entered 'No (N)'                                                                                                                                                                                                                      | System | 31 Aug 2020 14:18:12 |

US3742169

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 26 Nov 2020 11:15:04

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-08-31T10:18:09', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'c3ce0460-9012-4407-9a5e-a695ec2f839c' | System | 31 Aug 2020 14:18:12 |
| User entered '31 Aug 2020 10:18'                                                                                                                                                                                                           | System | 31 Aug 2020 14:18:12 |

US3742169

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 26 Nov 2020 11:15:04

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '31 Aug 2020 09:53' | System | 31 Aug 2020 14:08:19 |



US3742169

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 26 Nov 2020 11:15:04

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '31 Aug 2020 12:23' | System | 31 Aug 2020 14:08:19 |

US3742169

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 26 Nov 2020 11:15:04

[TIMEPOINT](#)

| Audit                                             | User   | Time (GMT)           |
|---------------------------------------------------|--------|----------------------|
| Data entry locked.                                | System | 31 Aug 2020 14:08:19 |
| User entered 'Day 1, after vaccination (at home)' | System | 31 Aug 2020 14:08:19 |

US3742169

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 26 Nov 2020 11:15:04

Was **TEMPERATURE** taken?

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-08-31T21:11:25', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: '773cb424-22a0-4c1b-8b7f-83699124b304' | System | 01 Sep 2020 01:11:57 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                     | System | 01 Sep 2020 01:11:57 |

US3742169

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 26 Nov 2020 11:15:04

Please record your **TEMPERATURE** in °F

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-08-31T21:11:33', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: '773cb424-22a0-4c1b-8b7f-83699124b304' | System | 01 Sep 2020 01:11:57 |
| User entered '98.0'                                                                                                                                                                                                                        | System | 01 Sep 2020 01:11:57 |

US3742169

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 26 Nov 2020 11:15:04

Was any **MEDICATION TAKEN** today for pain or fever?

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-08-31T21:11:41', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: '773cb424-22a0-4c1b-8b7f-83699124b304' | System | 01 Sep 2020 01:11:57 |
| User entered 'No (N)'                                                                                                                                                                                                                      | System | 01 Sep 2020 01:11:57 |

**US3742169**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 26 Nov 2020 11:15:04**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-08-31T21:11:54', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: '773cb424-22a0-4c1b-8b7f-83699124b304' | System | 01 Sep 2020 01:11:57 |
| User entered '31 Aug 2020 21:11'                                                                                                                                                                                                           | System | 01 Sep 2020 01:11:57 |

US3742169

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 26 Nov 2020 11:15:04

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '31 Aug 2020 13:18' | System | 31 Aug 2020 14:08:19 |

US3742169

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 26 Nov 2020 11:15:04**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '01 Sep 2020 11:59' | System | 31 Aug 2020 14:08:19 |



US3742169

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 11:15:04

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 31 Aug 2020 14:08:19 |
| User entered 'Day 2' | System | 31 Aug 2020 14:08:19 |

US3742169

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 11:15:04

Was **TEMPERATURE** taken?

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-09-01T23:59:57', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'b3851b0c-99ee-4870-878f-a79ef3339221' | System | 02 Sep 2020 04:00:23 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                     | System | 02 Sep 2020 04:00:23 |

US3742169

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 11:15:04

Please record your **TEMPERATURE** in °F

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-09-02T00:00:03', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'b3851b0c-99ee-4870-878f-a79ef3339221' | System | 02 Sep 2020 04:00:23 |
| User entered '97.3'                                                                                                                                                                                                                        | System | 02 Sep 2020 04:00:23 |

US3742169

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 11:15:04

Was any **MEDICATION TAKEN** today for pain or fever?

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-09-02T00:00:07', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'b3851b0c-99ee-4870-878f-a79ef3339221' | System | 02 Sep 2020 04:00:23 |
| User entered 'No (N)'                                                                                                                                                                                                                      | System | 02 Sep 2020 04:00:23 |

US3742169

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 11:15:04

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-09-02T00:00:12', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'b3851b0c-99ee-4870-878f-a79ef3339221' | System | 02 Sep 2020 04:00:23 |
| User entered '02 Sep 2020 00:00'                                                                                                                                                                                                           | System | 02 Sep 2020 04:00:23 |

US3742169

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 11:15:04

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '01 Sep 2020 12:00' | System | 31 Aug 2020 14:08:19 |

US3742169

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 11:15:04

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '02 Sep 2020 11:59' | System | 31 Aug 2020 14:08:19 |

US3742169

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 26 Nov 2020 11:15:04

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 31 Aug 2020 14:08:19 |
| User entered 'Day 3' | System | 31 Aug 2020 14:08:19 |



US3742169

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 26 Nov 2020 11:15:04

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '02 Sep 2020 12:00' | System | 31 Aug 2020 14:08:19 |

US3742169

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 26 Nov 2020 11:15:04**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '03 Sep 2020 11:59' | System | 31 Aug 2020 14:08:19 |

US3742169

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 11:15:04

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 31 Aug 2020 14:08:19 |
| User entered 'Day 4' | System | 31 Aug 2020 14:08:19 |

US3742169

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 11:15:04

Was **TEMPERATURE** taken?

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-09-04T11:14:39', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: '5459e3c8-c75e-45ff-addc-f04514abe139' | System | 04 Sep 2020 15:15:06 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                     | System | 04 Sep 2020 15:15:06 |

US3742169

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 11:15:04

Please record your **TEMPERATURE** in °F

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-09-04T11:14:50', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: '5459e3c8-c75e-45ff-addc-f04514abe139' | System | 04 Sep 2020 15:15:06 |
| User entered '98.3'                                                                                                                                                                                                                        | System | 04 Sep 2020 15:15:06 |

US3742169

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 11:15:04

Was any **MEDICATION TAKEN** today for pain or fever?

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-09-04T11:14:55', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: '5459e3c8-c75e-45ff-addc-f04514abe139' | System | 04 Sep 2020 15:15:06 |
| User entered 'No (N)'                                                                                                                                                                                                                      | System | 04 Sep 2020 15:15:06 |

US3742169

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 11:15:04

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-09-04T11:15:01', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: '5459e3c8-c75e-45ff-addc-f04514abe139' | System | 04 Sep 2020 15:15:06 |
| User entered '04 Sep 2020 11:15'                                                                                                                                                                                                           | System | 04 Sep 2020 15:15:06 |

US3742169

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 11:15:04

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '03 Sep 2020 12:00' | System | 31 Aug 2020 14:08:19 |



US3742169

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 11:15:04

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '04 Sep 2020 11:59' | System | 31 Aug 2020 14:08:19 |

US3742169

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 26 Nov 2020 11:15:04

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 31 Aug 2020 14:08:19 |
| User entered 'Day 5' | System | 31 Aug 2020 14:08:19 |

US3742169

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 26 Nov 2020 11:15:04

Was **TEMPERATURE** taken?

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-09-04T23:13:48', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'f7a5c7ef-ee77-47c4-924a-fda3bbd45b45' | System | 05 Sep 2020 03:14:11 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                     | System | 05 Sep 2020 03:14:11 |

US3742169

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 26 Nov 2020 11:15:04

Please record your **TEMPERATURE** in °F

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-09-04T23:13:58', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'f7a5c7ef-ee77-47c4-924a-fda3bbd45b45' | System | 05 Sep 2020 03:14:11 |
| User entered '97.5'                                                                                                                                                                                                                        | System | 05 Sep 2020 03:14:11 |

US3742169

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 26 Nov 2020 11:15:04

Was any **MEDICATION TAKEN** today for pain or fever?

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-09-04T23:14:03', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'f7a5c7ef-ee77-47c4-924a-fda3bbd45b45' | System | 05 Sep 2020 03:14:11 |
| User entered 'No (N)'                                                                                                                                                                                                                      | System | 05 Sep 2020 03:14:11 |

US3742169

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 26 Nov 2020 11:15:04

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-09-04T23:14:09', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'f7a5c7ef-ee77-47c4-924a-fda3bbd45b45' | System | 05 Sep 2020 03:14:11 |
| User entered '04 Sep 2020 23:14'                                                                                                                                                                                                           | System | 05 Sep 2020 03:14:11 |

US3742169

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 26 Nov 2020 11:15:04**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '04 Sep 2020 12:00' | System | 31 Aug 2020 14:08:19 |

US3742169

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 26 Nov 2020 11:15:04

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '05 Sep 2020 11:59' | System | 31 Aug 2020 14:08:19 |



US3742169

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 26 Nov 2020 11:15:04

[TIMEPOINT](#)

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 31 Aug 2020 14:08:19 |
| User entered 'Day 6' | System | 31 Aug 2020 14:08:19 |

US3742169

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 26 Nov 2020 11:15:04

Was **TEMPERATURE** taken?

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-09-06T09:05:00', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: '4a1676f4-26da-4e4f-b0c7-88a7f1bcc8cd' | System | 06 Sep 2020 13:05:15 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                     | System | 06 Sep 2020 13:05:15 |

US3742169

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 26 Nov 2020 11:15:04

Please record your **TEMPERATURE** in °F

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-09-06T09:05:06', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: '4a1676f4-26da-4e4f-b0c7-88a7f1bcc8cd' | System | 06 Sep 2020 13:05:15 |
| User entered '97.6'                                                                                                                                                                                                                        | System | 06 Sep 2020 13:05:15 |

US3742169

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 26 Nov 2020 11:15:04

Was any **MEDICATION TAKEN** today for pain or fever?

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-09-06T09:05:09', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: '4a1676f4-26da-4e4f-b0c7-88a7f1bcc8cd' | System | 06 Sep 2020 13:05:15 |
| User entered 'No (N)'                                                                                                                                                                                                                      | System | 06 Sep 2020 13:05:15 |

US3742169

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 26 Nov 2020 11:15:04

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-09-06T09:05:12', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: '4a1676f4-26da-4e4f-b0c7-88a7f1bcc8cd' | System | 06 Sep 2020 13:05:15 |
| User entered '06 Sep 2020 09:05'                                                                                                                                                                                                           | System | 06 Sep 2020 13:05:15 |

US3742169

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 26 Nov 2020 11:15:04

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '05 Sep 2020 12:00' | System | 31 Aug 2020 14:08:19 |

US3742169

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 26 Nov 2020 11:15:04

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '06 Sep 2020 11:59' | System | 31 Aug 2020 14:08:19 |

US3742169

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 26 Nov 2020 11:15:04

[TIMEPOINT](#)

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 31 Aug 2020 14:08:19 |
| User entered 'Day 7' | System | 31 Aug 2020 14:08:19 |



US3742169

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 26 Nov 2020 11:15:04

Was **TEMPERATURE** taken?

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-09-07T10:42:32', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: '151cffc4-8b71-4eeb-8300-c7c38b7ff946' | System | 07 Sep 2020 14:42:50 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                     | System | 07 Sep 2020 14:42:50 |

US3742169

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 26 Nov 2020 11:15:04

Please record your **TEMPERATURE** in °F

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-09-07T10:42:38', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: '151cffc4-8b71-4eeb-8300-c7c38b7ff946' | System | 07 Sep 2020 14:42:50 |
| User entered '98.1'                                                                                                                                                                                                                        | System | 07 Sep 2020 14:42:50 |

US3742169

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 26 Nov 2020 11:15:04

Was any **MEDICATION TAKEN** today for pain or fever?

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-09-07T10:42:42', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: '151cffc4-8b71-4eeb-8300-c7c38b7ff946' | System | 07 Sep 2020 14:42:50 |
| User entered 'No (N)'                                                                                                                                                                                                                      | System | 07 Sep 2020 14:42:50 |

US3742169

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 26 Nov 2020 11:15:04

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-09-07T10:42:45', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: '151cffc4-8b71-4eeb-8300-c7c38b7ff946' | System | 07 Sep 2020 14:42:50 |
| User entered '07 Sep 2020 10:42'                                                                                                                                                                                                           | System | 07 Sep 2020 14:42:50 |

US3742169

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 26 Nov 2020 11:15:04**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '06 Sep 2020 12:00' | System | 31 Aug 2020 14:08:19 |

US3742169

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 26 Nov 2020 11:15:04**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '07 Sep 2020 11:59' | System | 31 Aug 2020 14:08:19 |

US3742169

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 11:15:04

**TIMEPOINT**

| Audit                                                                | User   | Time (GMT)           |
|----------------------------------------------------------------------|--------|----------------------|
| Data entry locked.                                                   | System | 31 Aug 2020 14:08:19 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 31 Aug 2020 14:08:19 |

US3742169

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 11:15:04

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-08-31T10:18:19', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'ec48bce6-1a07-4814-834a-d5683b4577c0' | System | 31 Aug 2020 14:18:45 |
| User entered 'None (1)'                                                                                                                                                                                                                    | System | 31 Aug 2020 14:18:45 |



US3742169

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 11:15:04

Is there any REDNESS AT INJECTION SITE?

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-08-31T10:18:25', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'ec48bce6-1a07-4814-834a-d5683b4577c0' | System | 31 Aug 2020 14:18:45 |
| User entered 'No (N)'                                                                                                                                                                                                                      | System | 31 Aug 2020 14:18:45 |

US3742169

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 11:15:04

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-08-31T10:18:33', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'ec48bce6-1a07-4814-834a-d5683b4577c0' | System | 31 Aug 2020 14:18:45 |
| User entered 'No (N)'                                                                                                                                                                                                                      | System | 31 Aug 2020 14:18:45 |

US3742169

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 11:15:04

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-08-31T10:18:38', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'ec48bce6-1a07-4814-834a-d5683b4577c0' | System | 31 Aug 2020 14:18:45 |
| User entered 'None (1)'                                                                                                                                                                                                                    | System | 31 Aug 2020 14:18:45 |

US3742169

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 11:15:04

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-08-31T10:18:41', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'ec48bce6-1a07-4814-834a-d5683b4577c0' | System | 31 Aug 2020 14:18:45 |
| User entered '31 Aug 2020 10:18'                                                                                                                                                                                                           | System | 31 Aug 2020 14:18:45 |

US3742169

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 11:15:04

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '31 Aug 2020 09:53' | System | 31 Aug 2020 14:08:19 |

US3742169

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 11:15:04**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '31 Aug 2020 12:23' | System | 31 Aug 2020 14:08:19 |

US3742169

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 26 Nov 2020 11:15:04

**TIMEPOINT**

| Audit                                             | User   | Time (GMT)           |
|---------------------------------------------------|--------|----------------------|
| Data entry locked.                                | System | 31 Aug 2020 14:08:19 |
| User entered 'Day 1, after vaccination (at home)' | System | 31 Aug 2020 14:08:19 |

US3742169

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 26 Nov 2020 11:15:04

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-08-31T21:12:49', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'd37c9a9b-4dfa-43e7-9d38-69cbf53e4799' | System | 01 Sep 2020 01:14:43 |
| User entered 'Does not interfere with activity (2)'                                                                                                                                                                                        | System | 01 Sep 2020 01:14:43 |



US3742169

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 26 Nov 2020 11:15:04

Is there any REDNESS AT INJECTION SITE?

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-08-31T21:12:55', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'd37c9a9b-4dfa-43e7-9d38-69cbf53e4799' | System | 01 Sep 2020 01:14:43 |
| User entered 'No (N)'                                                                                                                                                                                                                      | System | 01 Sep 2020 01:14:43 |

US3742169

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 26 Nov 2020 11:15:04

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-08-31T21:13:01', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'd37c9a9b-4dfa-43e7-9d38-69cbf53e4799' | System | 01 Sep 2020 01:14:43 |
| User entered 'No (N)'                                                                                                                                                                                                                      | System | 01 Sep 2020 01:14:43 |

US3742169

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 26 Nov 2020 11:15:04

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-08-31T21:14:31', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'd37c9a9b-4dfa-43e7-9d38-69cbf53e4799' | System | 01 Sep 2020 01:14:43 |
| User entered 'Does not interfere with activity (2)'                                                                                                                                                                                        | System | 01 Sep 2020 01:14:43 |

**US3742169**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 11:15:04**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-08-31T21:14:40', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'd37c9a9b-4dfa-43e7-9d38-69cbf53e4799' | System | 01 Sep 2020 01:14:43 |
| User entered '31 Aug 2020 21:14'                                                                                                                                                                                                           | System | 01 Sep 2020 01:14:43 |

US3742169

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 11:15:04**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '31 Aug 2020 13:18' | System | 31 Aug 2020 14:08:19 |

US3742169

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 11:15:04**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '01 Sep 2020 11:59' | System | 31 Aug 2020 14:08:19 |

US3742169

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 26 Nov 2020 11:15:04

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 31 Aug 2020 14:08:19 |
| User entered 'Day 2' | System | 31 Aug 2020 14:08:19 |

US3742169

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 26 Nov 2020 11:15:04

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-09-02T00:00:23', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'decee5b6-4938-466c-af8c-a39da513356d' | System | 02 Sep 2020 04:00:52 |
| User entered 'Does not interfere with activity (2)'                                                                                                                                                                                        | System | 02 Sep 2020 04:00:52 |



US3742169

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 26 Nov 2020 11:15:04

Is there any REDNESS AT INJECTION SITE?

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-09-02T00:00:29', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'decee5b6-4938-466c-af8c-a39da513356d' | System | 02 Sep 2020 04:00:52 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                     | System | 02 Sep 2020 04:00:52 |

US3742169

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 26 Nov 2020 11:15:04

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

| Audit                                                                                                                                                                                                                                                       | User   | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-09-02T00:00:36', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'decee5b6-4938-466c-af8c-a39da513356d' User entered '3' | System | 02 Sep 2020 04:00:52 |

US3742169

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 26 Nov 2020 11:15:04

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-09-02T00:00:40', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'decee5b6-4938-466c-af8c-a39da513356d' | System | 02 Sep 2020 04:00:52 |
| User entered 'No (N)'                                                                                                                                                                                                                      | System | 02 Sep 2020 04:00:52 |

US3742169

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 26 Nov 2020 11:15:04

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-09-02T00:00:43', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'decee5b6-4938-466c-af8c-a39da513356d' | System | 02 Sep 2020 04:00:52 |
| User entered 'Does not interfere with activity (2)'                                                                                                                                                                                        | System | 02 Sep 2020 04:00:52 |

US3742169

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 26 Nov 2020 11:15:04

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-09-02T00:00:47', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'decee5b6-4938-466c-af8c-a39da513356d' | System | 02 Sep 2020 04:00:52 |
| User entered '02 Sep 2020 00:00'                                                                                                                                                                                                           | System | 02 Sep 2020 04:00:52 |

US3742169

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 11:15:04**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '01 Sep 2020 12:00' | System | 31 Aug 2020 14:08:19 |

US3742169

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 11:15:04**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '02 Sep 2020 11:59' | System | 31 Aug 2020 14:08:19 |

US3742169

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 26 Nov 2020 11:15:04

[TIMEPOINT](#)

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 31 Aug 2020 14:08:19 |
| User entered 'Day 3' | System | 31 Aug 2020 14:08:19 |



US3742169

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 11:15:04**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '02 Sep 2020 12:00' | System | 31 Aug 2020 14:08:19 |

US3742169

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 11:15:04**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '03 Sep 2020 11:59' | System | 31 Aug 2020 14:08:19 |

US3742169

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 26 Nov 2020 11:15:04

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 31 Aug 2020 14:08:19 |
| User entered 'Day 4' | System | 31 Aug 2020 14:08:19 |

US3742169

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 26 Nov 2020 11:15:04

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-09-04T11:15:07', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: '385d22c9-f3ed-4cd1-a400-4684742dcfee' | System | 04 Sep 2020 15:15:54 |
| User entered 'None (1)'                                                                                                                                                                                                                    | System | 04 Sep 2020 15:15:54 |

US3742169

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 26 Nov 2020 11:15:04

Is there any REDNESS AT INJECTION SITE?

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-09-04T11:15:12', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: '385d22c9-f3ed-4cd1-a400-4684742dcfee' | System | 04 Sep 2020 15:15:54 |
| User entered 'No (N)'                                                                                                                                                                                                                      | System | 04 Sep 2020 15:15:54 |

US3742169

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 26 Nov 2020 11:15:04

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-09-04T11:15:21', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: '385d22c9-f3ed-4cd1-a400-4684742dcfee' | System | 04 Sep 2020 15:15:54 |
| User entered 'No (N)'                                                                                                                                                                                                                      | System | 04 Sep 2020 15:15:54 |

US3742169

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 26 Nov 2020 11:15:04

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-09-04T11:15:32', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: '385d22c9-f3ed-4cd1-a400-4684742dcfee' | System | 04 Sep 2020 15:15:54 |
| User entered 'Does not interfere with activity (2)'                                                                                                                                                                                        | System | 04 Sep 2020 15:15:54 |

US3742169

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 26 Nov 2020 11:15:04

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-09-04T11:15:52', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: '385d22c9-f3ed-4cd1-a400-4684742dcfee' | System | 04 Sep 2020 15:15:54 |
| User entered '04 Sep 2020 11:15'                                                                                                                                                                                                           | System | 04 Sep 2020 15:15:54 |



US3742169

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 11:15:04**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '03 Sep 2020 12:00' | System | 31 Aug 2020 14:08:19 |

US3742169

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 26 Nov 2020 11:15:04

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '04 Sep 2020 11:59' | System | 31 Aug 2020 14:08:19 |

US3742169

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 26 Nov 2020 11:15:04

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 31 Aug 2020 14:08:19 |
| User entered 'Day 5' | System | 31 Aug 2020 14:08:19 |

US3742169

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 26 Nov 2020 11:15:04

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-09-04T23:14:16', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'bfc9fd29-9af5-49e2-9b33-754acbc53231' | System | 05 Sep 2020 03:15:08 |
| User entered 'None (1)'                                                                                                                                                                                                                    | System | 05 Sep 2020 03:15:08 |

US3742169

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 26 Nov 2020 11:15:04

Is there any REDNESS AT INJECTION SITE?

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-09-04T23:14:27', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'bfc9fd29-9af5-49e2-9b33-754acbc53231' | System | 05 Sep 2020 03:15:08 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                     | System | 05 Sep 2020 03:15:08 |

US3742169

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 26 Nov 2020 11:15:04

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

| Audit                                                                                                                                                                                                                                                       | User   | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-09-04T23:14:39', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'bfc9fd29-9af5-49e2-9b33-754acbc53231' User entered '3' | System | 05 Sep 2020 03:15:08 |

US3742169

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 26 Nov 2020 11:15:04

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-09-04T23:14:43', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'bfc9fd29-9af5-49e2-9b33-754acbc53231' | System | 05 Sep 2020 03:15:08 |
| User entered 'No (N)'                                                                                                                                                                                                                      | System | 05 Sep 2020 03:15:08 |

US3742169

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 26 Nov 2020 11:15:04

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-09-04T23:14:59', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'bfc9fd29-9af5-49e2-9b33-754acbc53231' | System | 05 Sep 2020 03:15:08 |
| User entered 'None (1)'                                                                                                                                                                                                                    | System | 05 Sep 2020 03:15:08 |



US3742169

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 26 Nov 2020 11:15:04

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-09-04T23:15:03', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'bfc9fd29-9af5-49e2-9b33-754acbc53231' | System | 05 Sep 2020 03:15:08 |
| User entered '04 Sep 2020 23:15'                                                                                                                                                                                                           | System | 05 Sep 2020 03:15:08 |

US3742169

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 11:15:04**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '04 Sep 2020 12:00' | System | 31 Aug 2020 14:08:19 |

US3742169

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 11:15:04**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '05 Sep 2020 11:59' | System | 31 Aug 2020 14:08:19 |

US3742169

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 26 Nov 2020 11:15:04

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 31 Aug 2020 14:08:19 |
| User entered 'Day 6' | System | 31 Aug 2020 14:08:19 |

US3742169

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 26 Nov 2020 11:15:04

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-09-06T09:05:19', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'd37ca948-fc97-44d6-8fb1-f58a27853bd0' | System | 06 Sep 2020 13:05:35 |
| User entered 'None (1)'                                                                                                                                                                                                                    | System | 06 Sep 2020 13:05:35 |

US3742169

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 26 Nov 2020 11:15:04

Is there any REDNESS AT INJECTION SITE?

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-09-06T09:05:23', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'd37ca948-fc97-44d6-8fb1-f58a27853bd0' | System | 06 Sep 2020 13:05:35 |
| User entered 'No (N)'                                                                                                                                                                                                                      | System | 06 Sep 2020 13:05:35 |

US3742169

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 26 Nov 2020 11:15:04

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-09-06T09:05:26', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'd37ca948-fc97-44d6-8fb1-f58a27853bd0' | System | 06 Sep 2020 13:05:35 |
| User entered 'No (N)'                                                                                                                                                                                                                      | System | 06 Sep 2020 13:05:35 |

US3742169

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 26 Nov 2020 11:15:04

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-09-06T09:05:29', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'd37ca948-fc97-44d6-8fb1-f58a27853bd0' | System | 06 Sep 2020 13:05:35 |
| User entered 'None (1)'                                                                                                                                                                                                                    | System | 06 Sep 2020 13:05:35 |



US3742169

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 26 Nov 2020 11:15:04

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-09-06T09:05:32', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'd37ca948-fc97-44d6-8fb1-f58a27853bd0' | System | 06 Sep 2020 13:05:35 |
| User entered '06 Sep 2020 09:05'                                                                                                                                                                                                           | System | 06 Sep 2020 13:05:35 |

US3742169

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 11:15:04**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '05 Sep 2020 12:00' | System | 31 Aug 2020 14:08:19 |

US3742169

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 11:15:04**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '06 Sep 2020 11:59' | System | 31 Aug 2020 14:08:19 |

US3742169

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 26 Nov 2020 11:15:04

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 31 Aug 2020 14:08:19 |
| User entered 'Day 7' | System | 31 Aug 2020 14:08:19 |

US3742169

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 26 Nov 2020 11:15:04

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-09-07T10:42:57', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'ba50c59d-d3e5-429c-bb0e-43d5e753d38c' | System | 07 Sep 2020 14:43:33 |
| User entered 'None (1)'                                                                                                                                                                                                                    | System | 07 Sep 2020 14:43:33 |

US3742169

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 26 Nov 2020 11:15:04

Is there any REDNESS AT INJECTION SITE?

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-09-07T10:43:00', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'ba50c59d-d3e5-429c-bb0e-43d5e753d38c' | System | 07 Sep 2020 14:43:33 |
| User entered 'No (N)'                                                                                                                                                                                                                      | System | 07 Sep 2020 14:43:33 |

US3742169

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 26 Nov 2020 11:15:04

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-09-07T10:43:09', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'ba50c59d-d3e5-429c-bb0e-43d5e753d38c' | System | 07 Sep 2020 14:43:33 |
| User entered 'No (N)'                                                                                                                                                                                                                      | System | 07 Sep 2020 14:43:33 |

US3742169

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 26 Nov 2020 11:15:04

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-09-07T10:43:27', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'ba50c59d-d3e5-429c-bb0e-43d5e753d38c' | System | 07 Sep 2020 14:43:33 |
| User entered 'None (1)'                                                                                                                                                                                                                    | System | 07 Sep 2020 14:43:33 |



US3742169

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 26 Nov 2020 11:15:04

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-09-07T10:43:29', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'ba50c59d-d3e5-429c-bb0e-43d5e753d38c' | System | 07 Sep 2020 14:43:33 |
| User entered '07 Sep 2020 10:43'                                                                                                                                                                                                           | System | 07 Sep 2020 14:43:33 |

US3742169

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 11:15:04**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '06 Sep 2020 12:00' | System | 31 Aug 2020 14:08:19 |

US3742169

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 26 Nov 2020 11:15:04

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '07 Sep 2020 11:59' | System | 31 Aug 2020 14:08:19 |

US3742169

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 11:15:04

**TIMEPOINT**

| Audit                                                                | User   | Time (GMT)           |
|----------------------------------------------------------------------|--------|----------------------|
| Data entry locked.                                                   | System | 31 Aug 2020 14:08:19 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 31 Aug 2020 14:08:19 |

**US3742169**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 11:15:04**

**HEADACHE**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-08-31T10:18:47', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: '38928d7e-43a0-4f3b-ae8f-4e46f3d19f07' | System | 31 Aug 2020 14:19:10 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System | 31 Aug 2020 14:19:10 |

US3742169

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 11:15:04

**FATIGUE**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-08-31T10:18:51', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: '38928d7e-43a0-4f3b-ae8f-4e46f3d19f07' | System | 31 Aug 2020 14:19:10 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System | 31 Aug 2020 14:19:10 |

US3742169

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 11:15:04

**MUSCLE ACHES ALL OVER BODY**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-08-31T10:18:55', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: '38928d7e-43a0-4f3b-ae8f-4e46f3d19f07' | System | 31 Aug 2020 14:19:10 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System | 31 Aug 2020 14:19:10 |

US3742169

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 11:15:04

**JOINT ACHES IN SEVERAL JOINTS**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-08-31T10:18:58', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: '38928d7e-43a0-4f3b-ae8f-4e46f3d19f07' | System | 31 Aug 2020 14:19:10 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System | 31 Aug 2020 14:19:10 |



US3742169

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 11:15:04

**NAUSEA/VOMITING**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-08-31T10:19:01', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: '38928d7e-43a0-4f3b-ae8f-4e46f3d19f07' | System | 31 Aug 2020 14:19:10 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System | 31 Aug 2020 14:19:10 |

US3742169

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 11:15:04

CHILLS

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-08-31T10:19:03', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: '38928d7e-43a0-4f3b-ae8f-4e46f3d19f07' | System | 31 Aug 2020 14:19:10 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System | 31 Aug 2020 14:19:10 |

US3742169

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 11:15:04

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-08-31T10:19:06', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: '38928d7e-43a0-4f3b-ae8f-4e46f3d19f07' | System | 31 Aug 2020 14:19:10 |
| User entered 'No (N)'                                                                                                                                                                                                                      | System | 31 Aug 2020 14:19:10 |

US3742169

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 11:15:04

[PC Time stamp](#)

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-08-31T10:19:09', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: '38928d7e-43a0-4f3b-ae8f-4e46f3d19f07' | System | 31 Aug 2020 14:19:10 |
| User entered '31 Aug 2020 10:19'                                                                                                                                                                                                           | System | 31 Aug 2020 14:19:10 |

US3742169

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 11:15:04

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '31 Aug 2020 09:53' | System | 31 Aug 2020 14:08:19 |

US3742169

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 11:15:04

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '31 Aug 2020 12:23' | System | 31 Aug 2020 14:08:19 |

US3742169

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 11:15:04

**TIMEPOINT**

| Audit                                             | User   | Time (GMT)           |
|---------------------------------------------------|--------|----------------------|
| Data entry locked.                                | System | 31 Aug 2020 14:08:19 |
| User entered 'Day 1, after vaccination (at home)' | System | 31 Aug 2020 14:08:19 |

**US3742169**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 11:15:04**

**HEADACHE**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-08-31T21:16:45', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'e5d4861f-1796-424f-9bc3-f8553c1785c5' | System | 01 Sep 2020 01:18:08 |
| User entered 'No interference with activity (1)'                                                                                                                                                                                           | System | 01 Sep 2020 01:18:08 |



**US3742169**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 11:15:04**

**FATIGUE**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-08-31T21:16:42', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'e5d4861f-1796-424f-9bc3-f8553c1785c5' | System | 01 Sep 2020 01:18:08 |
| User entered 'No interference with activity (1)'                                                                                                                                                                                           | System | 01 Sep 2020 01:18:08 |

US3742169

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 11:15:04

**MUSCLE ACHES ALL OVER BODY**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-08-31T21:16:55', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'e5d4861f-1796-424f-9bc3-f8553c1785c5' | System | 01 Sep 2020 01:18:08 |
| User entered 'Some interference with activity (2)'                                                                                                                                                                                         | System | 01 Sep 2020 01:18:08 |

US3742169

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 11:15:04

**JOINT ACHES IN SEVERAL JOINTS**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-08-31T21:17:04', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'e5d4861f-1796-424f-9bc3-f8553c1785c5' | System | 01 Sep 2020 01:18:08 |
| User entered 'Some interference with activity (2)'                                                                                                                                                                                         | System | 01 Sep 2020 01:18:08 |

US3742169

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 11:15:04

**NAUSEA/VOMITING**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-08-31T21:17:12', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'e5d4861f-1796-424f-9bc3-f8553c1785c5' | System | 01 Sep 2020 01:18:08 |
| User entered 'No interference with activity or 1-2 episodes/24 hours (1)'                                                                                                                                                                  | System | 01 Sep 2020 01:18:08 |

US3742169

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 11:15:04

CHILLS

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-08-31T21:17:55', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'e5d4861f-1796-424f-9bc3-f8553c1785c5' | System | 01 Sep 2020 01:18:08 |
| User entered 'Some interference with activity not requiring medical attention (2)'                                                                                                                                                         | System | 01 Sep 2020 01:18:08 |

US3742169

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 11:15:04

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-08-31T21:18:01', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'e5d4861f-1796-424f-9bc3-f8553c1785c5' | System | 01 Sep 2020 01:18:08 |
| User entered 'No (N)'                                                                                                                                                                                                                      | System | 01 Sep 2020 01:18:08 |

**US3742169**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 11:15:04**

[PC Time stamp](#)

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-08-31T21:18:07', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'e5d4861f-1796-424f-9bc3-f8553c1785c5' | System | 01 Sep 2020 01:18:08 |
| User entered '31 Aug 2020 21:18'                                                                                                                                                                                                           | System | 01 Sep 2020 01:18:08 |

US3742169

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 11:15:04

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '31 Aug 2020 13:18' | System | 31 Aug 2020 14:08:19 |



US3742169

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 11:15:04

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '01 Sep 2020 11:59' | System | 31 Aug 2020 14:08:19 |

US3742169

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 11:15:04

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 31 Aug 2020 14:08:19 |
| User entered 'Day 2' | System | 31 Aug 2020 14:08:19 |

**US3742169**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 11:15:04**

**HEADACHE**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-09-02T00:01:04', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'fe009847-4e0e-41fa-ae21-f338f81a2af3' | System | 02 Sep 2020 04:01:54 |
| User entered 'No interference with activity (1)'                                                                                                                                                                                           | System | 02 Sep 2020 04:01:54 |

US3742169

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 11:15:04

**FATIGUE**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-09-02T00:01:12', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'fe009847-4e0e-41fa-ae21-f338f81a2af3' | System | 02 Sep 2020 04:01:54 |
| User entered 'Some interference with activity (2)'                                                                                                                                                                                         | System | 02 Sep 2020 04:01:54 |

US3742169

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 11:15:04

**MUSCLE ACHES ALL OVER BODY**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-09-02T00:01:17', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'fe009847-4e0e-41fa-ae21-f338f81a2af3' | System | 02 Sep 2020 04:01:54 |
| User entered 'Some interference with activity (2)'                                                                                                                                                                                         | System | 02 Sep 2020 04:01:54 |

US3742169

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 11:15:04

**JOINT ACHES IN SEVERAL JOINTS**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-09-02T00:01:20', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'fe009847-4e0e-41fa-ae21-f338f81a2af3' | System | 02 Sep 2020 04:01:54 |
| User entered 'No interference with activity (1)'                                                                                                                                                                                           | System | 02 Sep 2020 04:01:54 |

US3742169

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 11:15:04

**NAUSEA/VOMITING**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-09-02T00:01:30', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'fe009847-4e0e-41fa-ae21-f338f81a2af3' | System | 02 Sep 2020 04:01:54 |
| User entered 'No interference with activity or 1-2 episodes/24 hours (1)'                                                                                                                                                                  | System | 02 Sep 2020 04:01:54 |

US3742169

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 11:15:04

**CHILLS**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-09-02T00:01:38', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'fe009847-4e0e-41fa-ae21-f338f81a2af3' | System | 02 Sep 2020 04:01:54 |
| User entered 'Some interference with activity not requiring medical attention (2)'                                                                                                                                                         | System | 02 Sep 2020 04:01:54 |



US3742169

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 11:15:04

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-09-02T00:01:46', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'fe009847-4e0e-41fa-ae21-f338f81a2af3' | System | 02 Sep 2020 04:01:54 |
| User entered 'No (N)'                                                                                                                                                                                                                      | System | 02 Sep 2020 04:01:54 |

US3742169

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 11:15:04

[PC Time stamp](#)

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-09-02T00:01:49', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'fe009847-4e0e-41fa-ae21-f338f81a2af3' | System | 02 Sep 2020 04:01:54 |
| User entered '02 Sep 2020 00:01'                                                                                                                                                                                                           | System | 02 Sep 2020 04:01:54 |

US3742169

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 11:15:04

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '01 Sep 2020 12:00' | System | 31 Aug 2020 14:08:19 |

US3742169

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 11:15:04

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '02 Sep 2020 11:59' | System | 31 Aug 2020 14:08:19 |

US3742169

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 11:15:04

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 31 Aug 2020 14:08:19 |
| User entered 'Day 3' | System | 31 Aug 2020 14:08:19 |

US3742169

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 11:15:04

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '02 Sep 2020 12:00' | System | 31 Aug 2020 14:08:19 |

US3742169

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 11:15:04

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '03 Sep 2020 11:59' | System | 31 Aug 2020 14:08:19 |

US3742169

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 11:15:04

[TIMEPOINT](#)

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 31 Aug 2020 14:08:19 |
| User entered 'Day 4' | System | 31 Aug 2020 14:08:19 |



**US3742169**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 11:15:04**

**HEADACHE**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-09-04T11:16:06', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: '5ae300ad-e476-4a12-bc4f-001d770b5207' | System | 04 Sep 2020 15:16:55 |
| User entered 'No interference with activity (1)'                                                                                                                                                                                           | System | 04 Sep 2020 15:16:55 |

US3742169

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 11:15:04

**FATIGUE**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-09-04T11:16:10', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: '5ae300ad-e476-4a12-bc4f-001d770b5207' | System | 04 Sep 2020 15:16:55 |
| User entered 'No interference with activity (1)'                                                                                                                                                                                           | System | 04 Sep 2020 15:16:55 |

US3742169

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 11:15:04

**MUSCLE ACHES ALL OVER BODY**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-09-04T11:16:15', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: '5ae300ad-e476-4a12-bc4f-001d770b5207' | System | 04 Sep 2020 15:16:55 |
| User entered 'No interference with activity (1)'                                                                                                                                                                                           | System | 04 Sep 2020 15:16:55 |

US3742169

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 11:15:04

**JOINT ACHES IN SEVERAL JOINTS**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-09-04T11:16:19', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: '5ae300ad-e476-4a12-bc4f-001d770b5207' | System | 04 Sep 2020 15:16:55 |
| User entered 'No interference with activity (1)'                                                                                                                                                                                           | System | 04 Sep 2020 15:16:55 |

**US3742169**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 11:15:04**

**NAUSEA/VOMITING**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-09-04T11:16:25', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: '5ae300ad-e476-4a12-bc4f-001d770b5207' | System | 04 Sep 2020 15:16:55 |
| User entered 'No interference with activity or 1-2 episodes/24 hours (1)'                                                                                                                                                                  | System | 04 Sep 2020 15:16:55 |

US3742169

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 11:15:04

**CHILLS**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-09-04T11:16:39', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: '5ae300ad-e476-4a12-bc4f-001d770b5207' | System | 04 Sep 2020 15:16:55 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System | 04 Sep 2020 15:16:55 |

US3742169

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 11:15:04

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-09-04T11:16:42', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: '5ae300ad-e476-4a12-bc4f-001d770b5207' | System | 04 Sep 2020 15:16:55 |
| User entered 'No (N)'                                                                                                                                                                                                                      | System | 04 Sep 2020 15:16:55 |

US3742169

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 11:15:04

[PC Time stamp](#)

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-09-04T11:16:52', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: '5ae300ad-e476-4a12-bc4f-001d770b5207' | System | 04 Sep 2020 15:16:55 |
| User entered '04 Sep 2020 11:16'                                                                                                                                                                                                           | System | 04 Sep 2020 15:16:55 |



US3742169

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 11:15:04

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '03 Sep 2020 12:00' | System | 31 Aug 2020 14:08:19 |

US3742169

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 11:15:04

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '04 Sep 2020 11:59' | System | 31 Aug 2020 14:08:19 |

US3742169

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 11:15:04

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 31 Aug 2020 14:08:19 |
| User entered 'Day 5' | System | 31 Aug 2020 14:08:19 |

US3742169

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 11:15:04

**HEADACHE**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-09-04T23:15:10', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'cfcc26e0-c85a-43f6-b84a-102835e46fd9' | System | 05 Sep 2020 03:16:10 |
| User entered 'No interference with activity (1)'                                                                                                                                                                                           | System | 05 Sep 2020 03:16:10 |

US3742169

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 11:15:04

**FATIGUE**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-09-04T23:15:15', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'cfcc26e0-c85a-43f6-b84a-102835e46fd9' | System | 05 Sep 2020 03:16:10 |
| User entered 'No interference with activity (1)'                                                                                                                                                                                           | System | 05 Sep 2020 03:16:10 |

US3742169

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 11:15:04

**MUSCLE ACHES ALL OVER BODY**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-09-04T23:15:22', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'cfcc26e0-c85a-43f6-b84a-102835e46fd9' | System | 05 Sep 2020 03:16:10 |
| User entered 'No interference with activity (1)'                                                                                                                                                                                           | System | 05 Sep 2020 03:16:10 |

US3742169

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 11:15:04

**JOINT ACHES IN SEVERAL JOINTS**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-09-04T23:15:28', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'cfcc26e0-c85a-43f6-b84a-102835e46fd9' | System | 05 Sep 2020 03:16:10 |
| User entered 'Some interference with activity (2)'                                                                                                                                                                                         | System | 05 Sep 2020 03:16:10 |

US3742169

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 11:15:04

**NAUSEA/VOMITING**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-09-04T23:15:43', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'cfcc26e0-c85a-43f6-b84a-102835e46fd9' | System | 05 Sep 2020 03:16:10 |
| User entered 'Some interference with activity or >2 episodes/24 hours (2)'                                                                                                                                                                 | System | 05 Sep 2020 03:16:10 |



US3742169

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 11:15:04

CHILLS

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-09-04T23:15:58', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'cfcc26e0-c85a-43f6-b84a-102835e46fd9' | System | 05 Sep 2020 03:16:10 |
| User entered 'No interference with activity (1)'                                                                                                                                                                                           | System | 05 Sep 2020 03:16:10 |

US3742169

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 11:15:04

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-09-04T23:16:03', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'cfcc26e0-c85a-43f6-b84a-102835e46fd9' | System | 05 Sep 2020 03:16:10 |
| User entered 'No (N)'                                                                                                                                                                                                                      | System | 05 Sep 2020 03:16:10 |

US3742169

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 11:15:04

[PC Time stamp](#)

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-09-04T23:16:07', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'cfcc26e0-c85a-43f6-b84a-102835e46fd9' | System | 05 Sep 2020 03:16:10 |
| User entered '04 Sep 2020 23:16'                                                                                                                                                                                                           | System | 05 Sep 2020 03:16:10 |

US3742169

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 11:15:04

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '04 Sep 2020 12:00' | System | 31 Aug 2020 14:08:19 |

US3742169

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 11:15:04

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '05 Sep 2020 11:59' | System | 31 Aug 2020 14:08:19 |

US3742169

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 11:15:04

[TIMEPOINT](#)

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 31 Aug 2020 14:08:19 |
| User entered 'Day 6' | System | 31 Aug 2020 14:08:19 |

US3742169

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 11:15:04

**HEADACHE**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-09-06T09:05:38', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'd193f6f8-27ae-42c8-8d86-94a47684e909' | System | 06 Sep 2020 13:06:19 |
| User entered 'No interference with activity (1)'                                                                                                                                                                                           | System | 06 Sep 2020 13:06:19 |

US3742169

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 11:15:04

**FATIGUE**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-09-06T09:05:43', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'd193f6f8-27ae-42c8-8d86-94a47684e909' | System | 06 Sep 2020 13:06:19 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System | 06 Sep 2020 13:06:19 |



US3742169

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 11:15:04

**MUSCLE ACHES ALL OVER BODY**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-09-06T09:05:46', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'd193f6f8-27ae-42c8-8d86-94a47684e909' | System | 06 Sep 2020 13:06:19 |
| User entered 'No interference with activity (1)'                                                                                                                                                                                           | System | 06 Sep 2020 13:06:19 |

US3742169

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 11:15:04

**JOINT ACHES IN SEVERAL JOINTS**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-09-06T09:05:51', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'd193f6f8-27ae-42c8-8d86-94a47684e909' | System | 06 Sep 2020 13:06:19 |
| User entered 'No interference with activity (1)'                                                                                                                                                                                           | System | 06 Sep 2020 13:06:19 |

US3742169

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 11:15:04

**NAUSEA/VOMITING**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-09-06T09:05:55', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'd193f6f8-27ae-42c8-8d86-94a47684e909' | System | 06 Sep 2020 13:06:19 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System | 06 Sep 2020 13:06:19 |

US3742169

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 11:15:04

**CHILLS**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-09-06T09:05:59', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'd193f6f8-27ae-42c8-8d86-94a47684e909' | System | 06 Sep 2020 13:06:19 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System | 06 Sep 2020 13:06:19 |

US3742169

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 11:15:04

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-09-06T09:06:02', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'd193f6f8-27ae-42c8-8d86-94a47684e909' | System | 06 Sep 2020 13:06:19 |
| User entered 'No (N)'                                                                                                                                                                                                                      | System | 06 Sep 2020 13:06:19 |

US3742169

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 11:15:04

[PC Time stamp](#)

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-09-06T09:06:05', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'd193f6f8-27ae-42c8-8d86-94a47684e909' | System | 06 Sep 2020 13:06:19 |
| User entered '06 Sep 2020 09:06'                                                                                                                                                                                                           | System | 06 Sep 2020 13:06:19 |

US3742169

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 11:15:04

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '05 Sep 2020 12:00' | System | 31 Aug 2020 14:08:19 |

US3742169

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 11:15:04

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '06 Sep 2020 11:59' | System | 31 Aug 2020 14:08:19 |



US3742169

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 11:15:04

[TIMEPOINT](#)

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 31 Aug 2020 14:08:19 |
| User entered 'Day 7' | System | 31 Aug 2020 14:08:19 |

US3742169

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 11:15:04

**HEADACHE**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-09-07T10:43:42', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'bcda0a3e-bdc0-4b1f-9072-f2c36bd314ef' | System | 07 Sep 2020 14:44:19 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System | 07 Sep 2020 14:44:19 |

US3742169

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 11:15:04

**FATIGUE**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-09-07T10:43:46', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'bcda0a3e-bdc0-4b1f-9072-f2c36bd314ef' | System | 07 Sep 2020 14:44:19 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System | 07 Sep 2020 14:44:19 |

US3742169

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 11:15:04

**MUSCLE ACHES ALL OVER BODY**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-09-07T10:43:54', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'bcda0a3e-bdc0-4b1f-9072-f2c36bd314ef' | System | 07 Sep 2020 14:44:19 |
| User entered 'No interference with activity (1)'                                                                                                                                                                                           | System | 07 Sep 2020 14:44:19 |

US3742169

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 11:15:04

**JOINT ACHES IN SEVERAL JOINTS**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-09-07T10:43:58', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'bcda0a3e-bdc0-4b1f-9072-f2c36bd314ef' | System | 07 Sep 2020 14:44:19 |
| User entered 'No interference with activity (1)'                                                                                                                                                                                           | System | 07 Sep 2020 14:44:19 |

US3742169

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 11:15:04

**NAUSEA/VOMITING**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-09-07T10:44:05', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'bcda0a3e-bdc0-4b1f-9072-f2c36bd314ef' | System | 07 Sep 2020 14:44:19 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System | 07 Sep 2020 14:44:19 |

US3742169

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 11:15:04

**CHILLS**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-09-07T10:44:08', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'bcda0a3e-bdc0-4b1f-9072-f2c36bd314ef' | System | 07 Sep 2020 14:44:19 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System | 07 Sep 2020 14:44:19 |

US3742169

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 11:15:04

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-09-07T10:44:11', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'bcda0a3e-bdc0-4b1f-9072-f2c36bd314ef' | System | 07 Sep 2020 14:44:19 |
| User entered 'No (N)'                                                                                                                                                                                                                      | System | 07 Sep 2020 14:44:19 |



US3742169

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 11:15:04

[PC Time stamp](#)

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-09-07T10:44:15', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'bcda0a3e-bdc0-4b1f-9072-f2c36bd314ef' | System | 07 Sep 2020 14:44:19 |
| User entered '07 Sep 2020 10:44'                                                                                                                                                                                                           | System | 07 Sep 2020 14:44:19 |

US3742169

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 11:15:04

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '06 Sep 2020 12:00' | System | 31 Aug 2020 14:08:19 |

US3742169

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 11:15:04

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '07 Sep 2020 11:59' | System | 31 Aug 2020 14:08:19 |

US3742169

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(8)

Generated On: 26 Nov 2020 11:15:04

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 06 Sep 2020 13:06:19 |
| User entered 'Day 8' | System | 06 Sep 2020 13:06:19 |

US3742169

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(8)

Generated On: 26 Nov 2020 11:15:04

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '07 Sep 2020 12:00' | System | 06 Sep 2020 13:06:19 |

US3742169

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(8)

Generated On: 26 Nov 2020 11:15:04

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '08 Sep 2020 11:59' | System | 06 Sep 2020 13:06:19 |

US3742169

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(9)

Generated On: 26 Nov 2020 11:15:04

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 07 Sep 2020 14:44:19 |
| User entered 'Day 9' | System | 07 Sep 2020 14:44:19 |

US3742169

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(9)

Generated On: 26 Nov 2020 11:15:04

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-09-09T10:29:56', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'c3a2d239-b94c-42d8-90ce-601cbc018b70' | System | 09 Sep 2020 14:30:06 |
| User entered 'No interference with activity (1)'                                                                                                                                                                                           | System | 09 Sep 2020 14:30:06 |



US3742169

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(9)

Generated On: 26 Nov 2020 11:15:04

[PC Time stamp](#)

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-09-09T10:30:01', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'c3a2d239-b94c-42d8-90ce-601cbc018b70' | System | 09 Sep 2020 14:30:06 |
| User entered '09 Sep 2020 10:30'                                                                                                                                                                                                           | System | 09 Sep 2020 14:30:06 |

US3742169

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(9)

Generated On: 26 Nov 2020 11:15:04

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '08 Sep 2020 12:00' | System | 07 Sep 2020 14:44:19 |

US3742169

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(9)

Generated On: 26 Nov 2020 11:15:04

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '09 Sep 2020 11:59' | System | 07 Sep 2020 14:44:19 |

US3742169

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(10)

Generated On: 26 Nov 2020 11:15:04

**TIMEPOINT**

| Audit                 | User   | Time (GMT)           |
|-----------------------|--------|----------------------|
| Data entry locked.    | System | 09 Sep 2020 14:30:06 |
| User entered 'Day 10' | System | 09 Sep 2020 14:30:06 |

US3742169

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(10)

Generated On: 26 Nov 2020 11:15:04

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-09-10T06:14:28', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: '5e1f8967-69c5-4411-b73d-579f65b65f71' | System | 10 Sep 2020 10:14:37 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System | 10 Sep 2020 10:14:37 |

US3742169

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(10)

Generated On: 26 Nov 2020 11:15:04

[PC Time stamp](#)

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-09-10T06:14:33', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: '5e1f8967-69c5-4411-b73d-579f65b65f71' | System | 10 Sep 2020 10:14:37 |
| User entered '10 Sep 2020 06:14'                                                                                                                                                                                                           | System | 10 Sep 2020 10:14:37 |

US3742169

**Folder: Diary Dose 1 (1)**

**Form: MuscleAche\_Day(10)**

**Generated On: 26 Nov 2020 11:15:04**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '09 Sep 2020 12:00' | System | 09 Sep 2020 14:30:06 |

US3742169

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(10)

Generated On: 26 Nov 2020 11:15:04

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '10 Sep 2020 11:59' | System | 09 Sep 2020 14:30:06 |



US3742169

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(8)

Generated On: 26 Nov 2020 11:15:04

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 06 Sep 2020 13:06:19 |
| User entered 'Day 8' | System | 06 Sep 2020 13:06:19 |

US3742169

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(8)

Generated On: 26 Nov 2020 11:15:04

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '07 Sep 2020 12:00' | System | 06 Sep 2020 13:06:19 |

US3742169

**Folder: Diary Dose 1 (1)**

**Form: JointsAche\_Day(8)**

**Generated On: 26 Nov 2020 11:15:04**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '08 Sep 2020 11:59' | System | 06 Sep 2020 13:06:19 |

US3742169

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(9)

Generated On: 26 Nov 2020 11:15:04

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 07 Sep 2020 14:44:19 |
| User entered 'Day 9' | System | 07 Sep 2020 14:44:19 |

US3742169

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(9)

Generated On: 26 Nov 2020 11:15:04

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-09-09T10:30:07', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'a5da341d-1b29-4498-ae50-162335964cf4' | System | 09 Sep 2020 14:30:14 |
| User entered 'No interference with activity (1)'                                                                                                                                                                                           | System | 09 Sep 2020 14:30:14 |

US3742169

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(9)

Generated On: 26 Nov 2020 11:15:04

[PC Time stamp](#)

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-09-09T10:30:10', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'a5da341d-1b29-4498-ae50-162335964cf4' | System | 09 Sep 2020 14:30:14 |
| User entered '09 Sep 2020 10:30'                                                                                                                                                                                                           | System | 09 Sep 2020 14:30:14 |

US3742169

**Folder: Diary Dose 1 (1)**

**Form: JointsAche\_Day(9)**

**Generated On: 26 Nov 2020 11:15:04**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '08 Sep 2020 12:00' | System | 07 Sep 2020 14:44:19 |

US3742169

**Folder: Diary Dose 1 (1)**

**Form: JointsAche\_Day(9)**

**Generated On: 26 Nov 2020 11:15:04**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '09 Sep 2020 11:59' | System | 07 Sep 2020 14:44:19 |



US3742169

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(10)

Generated On: 26 Nov 2020 11:15:04

**TIMEPOINT**

| Audit                 | User   | Time (GMT)           |
|-----------------------|--------|----------------------|
| Data entry locked.    | System | 09 Sep 2020 14:30:14 |
| User entered 'Day 10' | System | 09 Sep 2020 14:30:14 |

US3742169

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(10)

Generated On: 26 Nov 2020 11:15:04

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-09-10T06:14:38', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: '23daf9f8-6c3a-4cf9-95e7-522b67e13b79' | System | 10 Sep 2020 10:14:44 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System | 10 Sep 2020 10:14:44 |

US3742169

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(10)

Generated On: 26 Nov 2020 11:15:04

[PC Time stamp](#)

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-09-10T06:14:41', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: '23daf9f8-6c3a-4cf9-95e7-522b67e13b79' | System | 10 Sep 2020 10:14:44 |
| User entered '10 Sep 2020 06:14'                                                                                                                                                                                                           | System | 10 Sep 2020 10:14:44 |

US3742169

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(10)

Generated On: 26 Nov 2020 11:15:04

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '09 Sep 2020 12:00' | System | 09 Sep 2020 14:30:14 |

US3742169

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(10)

Generated On: 26 Nov 2020 11:15:04

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '10 Sep 2020 11:59' | System | 09 Sep 2020 14:30:14 |

US3742169

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 26 Nov 2020 11:15:04

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 06 Sep 2020 13:06:19 |
| User entered 'Day 8' | System | 06 Sep 2020 13:06:19 |

US3742169

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 26 Nov 2020 11:15:04

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '07 Sep 2020 12:00' | System | 06 Sep 2020 13:06:19 |

US3742169

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 26 Nov 2020 11:15:04

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '08 Sep 2020 11:59' | System | 06 Sep 2020 13:06:19 |



US3742169

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(9)

Generated On: 26 Nov 2020 11:15:04

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 07 Sep 2020 14:44:19 |
| User entered 'Day 9' | System | 07 Sep 2020 14:44:19 |

US3742169

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(9)

Generated On: 26 Nov 2020 11:15:04

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-09-09T10:30:25', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: '0e4f307c-afda-4314-a406-ff5145478392' | System | 09 Sep 2020 14:30:32 |
| User entered 'No (N)'                                                                                                                                                                                                                      | System | 09 Sep 2020 14:30:32 |

**US3742169**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(9)**

**Generated On: 26 Nov 2020 11:15:04**

[PC Time stamp](#)

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-09-09T10:30:28', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: '0e4f307c-afda-4314-a406-ff5145478392' | System | 09 Sep 2020 14:30:32 |
| User entered '09 Sep 2020 10:30'                                                                                                                                                                                                           | System | 09 Sep 2020 14:30:32 |

US3742169

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(9)

Generated On: 26 Nov 2020 11:15:04

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '08 Sep 2020 12:00' | System | 07 Sep 2020 14:44:19 |

US3742169

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(9)

Generated On: 26 Nov 2020 11:15:04

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '09 Sep 2020 11:59' | System | 07 Sep 2020 14:44:19 |

US3742169

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(10)

Generated On: 26 Nov 2020 11:15:04

**TIMEPOINT**

| Audit                 | User   | Time (GMT)           |
|-----------------------|--------|----------------------|
| Data entry locked.    | System | 09 Sep 2020 14:30:06 |
| User entered 'Day 10' | System | 09 Sep 2020 14:30:06 |

US3742169

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(10)

Generated On: 26 Nov 2020 11:15:04

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-09-10T06:14:45', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: '5edc8a11-524e-42ea-abb3-bc398249392f' | System | 10 Sep 2020 10:14:50 |
| User entered 'No (N)'                                                                                                                                                                                                                      | System | 10 Sep 2020 10:14:50 |

**US3742169**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(10)**

**Generated On: 26 Nov 2020 11:15:04**

[PC Time stamp](#)

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-09-10T06:14:48', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: '5edc8a11-524e-42ea-abb3-bc398249392f' | System | 10 Sep 2020 10:14:50 |
| User entered '10 Sep 2020 06:14'                                                                                                                                                                                                           | System | 10 Sep 2020 10:14:50 |



US3742169

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(10)**

**Generated On: 26 Nov 2020 11:15:04**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '09 Sep 2020 12:00' | System | 09 Sep 2020 14:30:06 |

US3742169

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(10)

Generated On: 26 Nov 2020 11:15:04

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '10 Sep 2020 11:59' | System | 09 Sep 2020 14:30:06 |

US3742169

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:15:04

[Was Contact Attempted?](#)

| Audit                  | User                            | Time (GMT)           |
|------------------------|---------------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)                | 01 Oct 2020 20:25:15 |
| User entered 'Yes (Y)' | Faith Pa'ahana-Brown<br>(b) (4) | 09 Sep 2020 16:11:13 |

US3742169

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:15:04

Date of Contact or Contact Attempt (*dd MMM yyyy*)

| Audit                                                          | User                            | Time (GMT)           |
|----------------------------------------------------------------|---------------------------------|----------------------|
| DataPoint Un-verified.                                         | (b) (4), (b) (6)                | 10 Nov 2020 00:05:57 |
| User entered '09 Sep 2020' reason for change: Data Entry Error | (b) (4), (b) (6)                | 10 Nov 2020 00:05:57 |
| DataPoint Verified.                                            | (b) (4), (b) (6)                | 01 Oct 2020 20:25:15 |
| User entered '9 Sep 2020'                                      | Faith Pa'ahana-Brown<br>(b) (4) | 09 Sep 2020 16:11:13 |

US3742169

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 11:15:04**

[Please select one status for the follow-up contact](#)

| Audit                                      | User                            | Time (GMT)           |
|--------------------------------------------|---------------------------------|----------------------|
| DataPoint Verified.                        | (b) (4), (b) (6)                | 01 Oct 2020 20:25:15 |
| User entered 'Contact Made (CONTACT MADE)' | Faith Pa'ahana-Brown<br>(b) (4) | 09 Sep 2020 16:11:13 |

US3742169

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:15:04

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit               | User                 | Time (GMT)           |
|---------------------|----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)     | 01 Oct 2020 20:25:15 |
| User entered empty. | Faith Pa'ahana-Brown | 09 Sep 2020 16:11:13 |
|                     | (b) (4)              |                      |

US3742169

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:15:04

[Is the participant continuing to the next visit?](#)

| Audit                  | User                            | Time (GMT)           |
|------------------------|---------------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)                | 01 Oct 2020 20:25:33 |
| User entered 'Yes (Y)' | Faith Pa'ahana-Brown<br>(b) (4) | 09 Sep 2020 16:11:21 |

US3742169

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 11:15:04**

[Continuing Flag](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 09 Sep 2020 16:11:21 |



US3742169

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:15:04

[Was Contact Attempted?](#)

| Audit                  | User                            | Time (GMT)           |
|------------------------|---------------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)                | 14 Oct 2020 19:35:56 |
| User entered 'Yes (Y)' | Faith Pa'ahana-Brown<br>(b) (4) | 17 Sep 2020 14:56:43 |

US3742169

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 11:15:04**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

| Audit                      | User                            | Time (GMT)           |
|----------------------------|---------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                | 14 Oct 2020 19:35:56 |
| User entered '16 Sep 2020' | Faith Pa'ahana-Brown<br>(b) (4) | 17 Sep 2020 14:56:43 |

US3742169

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 11:15:04**

[Please select one status for the follow-up contact](#)

| Audit                                      | User                            | Time (GMT)           |
|--------------------------------------------|---------------------------------|----------------------|
| DataPoint Verified.                        | (b) (4), (b) (6)                | 14 Oct 2020 19:35:56 |
| User entered 'Contact Made (CONTACT MADE)' | Faith Pa'ahana-Brown<br>(b) (4) | 17 Sep 2020 14:56:43 |

US3742169

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:15:04

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit               | User                            | Time (GMT)           |
|---------------------|---------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                | 14 Oct 2020 19:35:56 |
| User entered empty. | Faith Pa'ahana-Brown<br>(b) (4) | 17 Sep 2020 14:56:43 |

US3742169

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:15:04

[Is the participant continuing to the next visit?](#)

| Audit                  | User                            | Time (GMT)           |
|------------------------|---------------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)                | 14 Oct 2020 19:36:01 |
| User entered 'Yes (Y)' | Faith Pa'ahana-Brown<br>(b) (4) | 17 Sep 2020 14:56:51 |

US3742169

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 11:15:04**

[Continuing Flag](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 17 Sep 2020 14:56:51 |

US3742169

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:15:04

[Was Contact Attempted?](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 14 Oct 2020 19:36:08 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 06 Oct 2020 14:03:38 |

US3742169

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:15:04

Date of Contact or Contact Attempt (*dd MMM yyyy*)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 14 Oct 2020 19:36:08 |
| User entered '23 Sep 2020' | (b) (4), (b) (6) | 06 Oct 2020 14:03:38 |



US3742169

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 11:15:04**

[Please select one status for the follow-up contact](#)

| Audit                                      | User             | Time (GMT)           |
|--------------------------------------------|------------------|----------------------|
| DataPoint Verified.                        | (b) (4), (b) (6) | 14 Oct 2020 19:36:08 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4), (b) (6) | 06 Oct 2020 14:03:38 |

US3742169

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:15:04

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 19:36:08 |
| User entered empty. | (b) (4), (b) (6) | 06 Oct 2020 14:03:38 |

US3742169

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:15:04

[Is the participant continuing to the next visit?](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 14 Oct 2020 19:36:13 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 06 Oct 2020 14:03:56 |

US3742169

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 11:15:04**

[Continuing Flag](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 06 Oct 2020 14:03:56 |

US3742169

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:15:04

[Was this visit performed?](#)

| Audit                                                                                    | User                    | Time (GMT)           |
|------------------------------------------------------------------------------------------|-------------------------|----------------------|
| User closed query 'per CDM: please complete exposure form' (Site from DM).               | (b) (4), (b) (6)        | 03 Nov 2020 12:34:23 |
| DataPoint Verified.                                                                      | (b) (4), (b) (6)        | 28 Oct 2020 15:54:48 |
| Query 'per CDM: please complete exposure form' answered with 'completed' (Site from DM). | Kaitlin Mason (b) (4)   | 28 Oct 2020 12:37:27 |
| User opened query 'per CDM: please complete exposure form' (Site from DM).               | (b) (4), (b) (6)        | 20 Oct 2020 15:15:41 |
| User entered 'Yes (Y)'                                                                   | Sherry McCammon (b) (4) | 13 Oct 2020 16:53:35 |

US3742169

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:15:04

[Visit date \(dd MMM yyyy\)](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)        | 28 Oct 2020 15:54:48 |
| User entered '5 Oct 2020' | Sherry McCammon (b) (4) | 13 Oct 2020 16:53:35 |
|                           | (b) (4)                 |                      |

US3742169

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:15:04

[Was visit performed at the participant's home or at the clinic?](#)

| Audit                          | User                               | Time (GMT)           |
|--------------------------------|------------------------------------|----------------------|
| DataPoint Verified.            | (b) (4), (b) (6)                   | 28 Oct 2020 15:54:48 |
| User entered 'Clinic (Clinic)' | Sherry McCammon (b) (4)<br>(b) (4) | 13 Oct 2020 16:53:35 |

US3742169

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:15:04

[Folder OID](#)

| Audit                 | User   | Time (GMT)           |
|-----------------------|--------|----------------------|
| User entered 'VISIT2' | System | 13 Oct 2020 16:53:35 |



US3742169

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:15:04

[Timepoint](#)

| Audit                                            | User                    | Time (GMT)           |
|--------------------------------------------------|-------------------------|----------------------|
| User accepted default value 'Pre-Dose (PREDOSE)' | Sherry McCammon (b) (4) | 13 Oct 2020 16:56:55 |
|                                                  | (b) (4)                 |                      |

US3742169

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:15:04

[Were vital signs assessed?](#)

| Audit                  | User                    | Time (GMT)           |
|------------------------|-------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)        | 28 Oct 2020 15:54:53 |
| User entered 'Yes (Y)' | Sherry McCammon (b) (4) | 13 Oct 2020 16:56:55 |
|                        | (b) (4)                 |                      |

US3742169

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:15:04

Date of assessment (*dd MMM yyyy*)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)        | 28 Oct 2020 15:54:53 |
| User entered '5 Oct 2020' | Sherry McCammon (b) (4) | 13 Oct 2020 16:56:55 |
|                           | (b) (4)                 |                      |

US3742169

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:15:04

Time of assessment (00:00-23:59)

| Audit                | User                    | Time (GMT)           |
|----------------------|-------------------------|----------------------|
| DataPoint Verified.  | (b) (4), (b) (6)        | 28 Oct 2020 15:54:53 |
| User entered '12:01' | Sherry McCammon (b) (4) | 13 Oct 2020 16:56:55 |
|                      | (b) (4)                 |                      |

US3742169

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:15:04

[Vital Signs Date and Time \(derived\)](#)

| Audit                           | User   | Time (GMT)           |
|---------------------------------|--------|----------------------|
| User entered '5 Oct 2020 12:01' | System | 13 Oct 2020 16:56:55 |

US3742169

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:15:04

Temperature (xxx.x)

| Audit                  | User                    | Time (GMT)           |
|------------------------|-------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)        | 28 Oct 2020 15:54:53 |
| User entered '097.9' F | Sherry McCammon (b) (4) | 13 Oct 2020 16:56:55 |
|                        | (b) (4)                 |                      |

US3742169

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:15:04

[Route of measurement](#)

| Audit                      | User                    | Time (GMT)           |
|----------------------------|-------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)        | 28 Oct 2020 15:54:53 |
| User entered 'Oral (Oral)' | Sherry McCammon (b) (4) | 13 Oct 2020 16:56:55 |
|                            | (b) (4)                 |                      |

US3742169

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:15:04

[If Other, specify](#)

| Audit               | User                    | Time (GMT)           |
|---------------------|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)        | 28 Oct 2020 15:54:53 |
| User entered empty. | Sherry McCammon (b) (4) | 13 Oct 2020 16:56:55 |
|                     | (b) (4)                 |                      |



US3742169

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:15:04

[Pulse \(xxx\)](#)

| Audit               | User                    | Time (GMT)           |
|---------------------|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)        | 28 Oct 2020 15:54:53 |
| User entered '066'  | Sherry McCammon (b) (4) | 13 Oct 2020 16:56:55 |
|                     | (b) (4)                 |                      |

US3742169

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:15:04

[Pulse units](#)

| Audit              | User   | Time (GMT)           |
|--------------------|--------|----------------------|
| User entered 'bpm' | System | 13 Oct 2020 16:56:55 |

US3742169

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:15:04

[Respiratory Rate \(xxx\)](#)

| Audit               | User                    | Time (GMT)           |
|---------------------|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)        | 28 Oct 2020 15:54:53 |
| User entered '15'   | Sherry McCammon (b) (4) | 13 Oct 2020 16:56:55 |
|                     | (b) (4)                 |                      |

US3742169

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:15:04

[Respiratory Rate units](#)

| Audit                      | User   | Time (GMT)           |
|----------------------------|--------|----------------------|
| User entered 'breaths/min' | System | 13 Oct 2020 16:56:55 |

US3742169

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:15:04

Systolic Blood Pressure (xxx)

| Audit               | User                    | Time (GMT)           |
|---------------------|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)        | 28 Oct 2020 15:54:53 |
| User entered '117'  | Sherry McCammon (b) (4) | 13 Oct 2020 16:56:55 |
|                     | (b) (4)                 |                      |

US3742169

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:15:04

[Systolic Blood Pressure units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 13 Oct 2020 16:56:55 |

US3742169

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:15:04

Diastolic Blood Pressure (xxx)

| Audit               | User                    | Time (GMT)           |
|---------------------|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)        | 28 Oct 2020 15:54:53 |
| User entered '083'  | Sherry McCammon (b) (4) | 13 Oct 2020 16:56:55 |
|                     | (b) (4)                 |                      |

US3742169

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 11:15:04**

[Diastolic Blood Pressure units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 13 Oct 2020 16:56:55 |



US3742169

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:15:04

[Timepoint](#)

| Audit                                              | User                    | Time (GMT)           |
|----------------------------------------------------|-------------------------|----------------------|
| User accepted default value 'Post-Dose (POSTDOSE)' | Sherry McCammon (b) (4) | 13 Oct 2020 16:56:55 |

US3742169

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:15:04

[Were vital signs assessed?](#)

| Audit                 | User                    | Time (GMT)           |
|-----------------------|-------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)        | 28 Oct 2020 15:54:53 |
| User entered 'No (N)' | Sherry McCammon (b) (4) | 13 Oct 2020 16:56:55 |
|                       | (b) (4)                 |                      |

US3742169

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:15:04

Date of assessment (*dd MMM yyyy*)

| Audit               | User                    | Time (GMT)           |
|---------------------|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)        | 28 Oct 2020 15:54:53 |
| User entered empty. | Sherry McCammon (b) (4) | 13 Oct 2020 16:56:55 |
|                     | (b) (4)                 |                      |

US3742169

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:15:04

Time of assessment (00:00-23:59)

| Audit               | User                    | Time (GMT)           |
|---------------------|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)        | 28 Oct 2020 15:54:53 |
| User entered empty. | Sherry McCammon (b) (4) | 13 Oct 2020 16:56:55 |
|                     | (b) (4)                 |                      |

US3742169

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:15:04

[Vital Signs Date and Time \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 13 Oct 2020 16:56:55 |

US3742169

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:15:04

Temperature (xxx.x)

| Audit               | User                    | Time (GMT)           |
|---------------------|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)        | 28 Oct 2020 15:54:53 |
| User entered empty. | Sherry McCammon (b) (4) | 13 Oct 2020 16:56:55 |
|                     | (b) (4)                 |                      |

US3742169

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:15:04

[Route of measurement](#)

| Audit               | User                    | Time (GMT)           |
|---------------------|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)        | 28 Oct 2020 15:54:53 |
| User entered empty. | Sherry McCammon (b) (4) | 13 Oct 2020 16:56:55 |
|                     | (b) (4)                 |                      |

US3742169

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:15:04

[If Other, specify](#)

| Audit               | User                    | Time (GMT)           |
|---------------------|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)        | 28 Oct 2020 15:54:53 |
| User entered empty. | Sherry McCammon (b) (4) | 13 Oct 2020 16:56:55 |
|                     | (b) (4)                 |                      |



US3742169

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:15:04

[Pulse \(xxx\)](#)

| Audit               | User                    | Time (GMT)           |
|---------------------|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)        | 28 Oct 2020 15:54:53 |
| User entered empty. | Sherry McCammon (b) (4) | 13 Oct 2020 16:56:55 |
|                     | (b) (4)                 |                      |

US3742169

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:15:04

[Pulse units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 13 Oct 2020 16:56:55 |

US3742169

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:15:04

[Respiratory Rate \(xxx\)](#)

| Audit               | User                    | Time (GMT)           |
|---------------------|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)        | 28 Oct 2020 15:54:53 |
| User entered empty. | Sherry McCammon (b) (4) | 13 Oct 2020 16:56:55 |
|                     | (b) (4)                 |                      |

US3742169

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:15:04

[Respiratory Rate units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 13 Oct 2020 16:56:55 |

US3742169

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:15:04

Systolic Blood Pressure (xxx)

| Audit               | User                    | Time (GMT)           |
|---------------------|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)        | 28 Oct 2020 15:54:53 |
| User entered empty. | Sherry McCammon (b) (4) | 13 Oct 2020 16:56:55 |
|                     | (b) (4)                 |                      |

US3742169

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:15:04

[Systolic Blood Pressure units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 13 Oct 2020 16:56:55 |

US3742169

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:15:04

Diastolic Blood Pressure (xxx)

| Audit               | User                    | Time (GMT)           |
|---------------------|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)        | 28 Oct 2020 15:54:53 |
| User entered empty. | Sherry McCammon (b) (4) | 13 Oct 2020 16:56:55 |
|                     | (b) (4)                 |                      |

US3742169

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 11:15:04**

[Diastolic Blood Pressure units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 13 Oct 2020 16:56:55 |



US3742169

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:15:04

[Was the physical examination performed?](#)

| Audit                  | User                    | Time (GMT)           |
|------------------------|-------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)        | 28 Oct 2020 15:54:57 |
| User entered 'Yes (Y)' | Sherry McCammon (b) (4) | 13 Oct 2020 16:58:15 |
|                        | (b) (4)                 |                      |

US3742169

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:15:04

Date of examination (dd MMM yyyy)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)        | 28 Oct 2020 15:54:57 |
| User entered '5 Oct 2020' | Sherry McCammon (b) (4) | 13 Oct 2020 16:58:15 |
|                           | (b) (4)                 |                      |

US3742169

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:15:04

[Was study treatment given?](#)

| Audit                 | User                  | Time (GMT)           |
|-----------------------|-----------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)      | 28 Oct 2020 15:55:25 |
| User entered 'No (N)' | Kaitlin Mason (b) (4) | 24 Oct 2020 15:42:35 |
|                       | (b) (4)               |                      |

US3742169

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:15:04

[If No, reason not given](#)

| Audit                                                                      | User                             | Time (GMT)           |
|----------------------------------------------------------------------------|----------------------------------|----------------------|
| DataPoint Verified.                                                        | (b) (4), (b) (6)                 | 28 Oct 2020 15:55:25 |
| User entered 'Physician withheld dose due to Adverse Event (PHYSICIAN AE)' | Kaitlin Mason (b) (4)<br>(b) (4) | 24 Oct 2020 15:42:35 |

US3742169

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:15:04

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

| Audit                              | User                             | Time (GMT)           |
|------------------------------------|----------------------------------|----------------------|
| DataPoint Verified.                | (b) (4), (b) (6)                 | 28 Oct 2020 15:55:25 |
| User entered 'WITHHELD DUE TO SAE' | Kaitlin Mason (b) (4)<br>(b) (4) | 24 Oct 2020 15:42:35 |

US3742169

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:15:04

[What was the study treatment?](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 24 Oct 2020 15:42:35 |

US3742169

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:15:04

[What was the treatment date? \(dd MMM yyyy\)](#)

| Audit               | User                  | Time (GMT)           |
|---------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)      | 28 Oct 2020 15:55:25 |
| User entered empty. | Kaitlin Mason (b) (4) | 24 Oct 2020 15:42:35 |
|                     | (b) (4)               |                      |

US3742169

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:15:04

[What was the treatment time? \(00:00-23:59\)](#)

| Audit               | User                  | Time (GMT)           |
|---------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)      | 28 Oct 2020 15:55:25 |
| User entered empty. | Kaitlin Mason (b) (4) | 24 Oct 2020 15:42:35 |
|                     | (b) (4)               |                      |



US3742169

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:15:04

[Treatment Date and Time \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 24 Oct 2020 15:42:35 |

US3742169

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:15:04

[Which arm was used to give treatment?](#)

| Audit               | User                  | Time (GMT)           |
|---------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)      | 28 Oct 2020 15:55:25 |
| User entered empty. | Kaitlin Mason (b) (4) | 24 Oct 2020 15:42:35 |
|                     | (b) (4)               |                      |

US3742169

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:15:04

[What was the frequency of the study treatment dosing?](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 28 Oct 2020 15:55:25 |
| User entered empty. | System           | 24 Oct 2020 15:42:35 |

US3742169

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:15:04

[What was the route of administration for the study treatment?](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 24 Oct 2020 15:42:35 |

US3742169

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:15:04

[Was the sample collected?](#)

| Audit                  | User                    | Time (GMT)           |
|------------------------|-------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)        | 28 Oct 2020 15:55:31 |
| User entered 'Yes (Y)' | Sherry McCammon (b) (4) | 13 Oct 2020 16:54:21 |
|                        | (b) (4)                 |                      |

US3742169

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:15:04

Collection date (dd MMM yyyy)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)        | 28 Oct 2020 15:55:31 |
| User entered '5 Oct 2020' | Sherry McCammon (b) (4) | 13 Oct 2020 16:54:21 |
|                           | (b) (4)                 |                      |

US3742169

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:15:04

Collection time (00:00-23:59)

| Audit                | User                    | Time (GMT)           |
|----------------------|-------------------------|----------------------|
| DataPoint Verified.  | (b) (4), (b) (6)        | 28 Oct 2020 15:55:31 |
| User entered '12:06' | Sherry McCammon (b) (4) | 13 Oct 2020 16:54:21 |
|                      | (b) (4)                 |                      |

US3742169

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:15:04

[Collection date and time \(derived\)](#)

| Audit                           | User   | Time (GMT)           |
|---------------------------------|--------|----------------------|
| User entered '5 Oct 2020 12:06' | System | 13 Oct 2020 16:54:21 |



US3742169

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 11:15:04

Collection date (dd MMM yyyy)

| Audit                                                                                                                                   | User                    | Time (GMT)           |
|-----------------------------------------------------------------------------------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                                                                                                     | (b) (4), (b) (6)        | 28 Oct 2020 16:00:47 |
| User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).                    | System                  | 13 Oct 2020 16:54:04 |
| Query 'The Collection Date is not equal to Visit Date. System Please review and reconcile.' answered by data change (Site from System). |                         | 13 Oct 2020 16:54:04 |
| User entered '5 Oct 2020' reason for change: Data Entry Error                                                                           | Sherry McCammon (b) (4) | 13 Oct 2020 16:54:04 |
| User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).                    | System                  | 13 Oct 2020 16:53:49 |
| User entered '13 Oct 2020'                                                                                                              | Sherry McCammon (b) (4) | 13 Oct 2020 16:53:49 |

US3742169

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:15:04

[Lab Test](#)

| Audit                                                        | User                    | Time (GMT)           |
|--------------------------------------------------------------|-------------------------|----------------------|
| User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)' | Sherry McCammon (b) (4) | 13 Oct 2020 16:53:49 |

US3742169

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:15:04

[Was the sample collected?](#)

| Audit                  | User                    | Time (GMT)           |
|------------------------|-------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)        | 28 Oct 2020 16:00:47 |
| User entered 'Yes (Y)' | Sherry McCammon (b) (4) | 13 Oct 2020 16:53:49 |
|                        | (b) (4)                 |                      |

US3742169

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:15:04

Collection time (00:00 - 23:59)

| Audit                | User                    | Time (GMT)           |
|----------------------|-------------------------|----------------------|
| DataPoint Verified.  | (b) (4), (b) (6)        | 28 Oct 2020 16:00:47 |
| User entered '12:05' | Sherry McCammon (b) (4) | 13 Oct 2020 16:53:49 |
|                      | (b) (4)                 |                      |

US3742169

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:15:04

[Collection date and time \(derived\)](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '5 Oct 2020 12:05'  | System | 13 Oct 2020 16:54:04 |
| User entered '13 Oct 2020 12:05' | System | 13 Oct 2020 16:53:49 |

US3742169

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:15:04

[Lab Test](#)

| Audit                                                        | User                    | Time (GMT)           |
|--------------------------------------------------------------|-------------------------|----------------------|
| User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)' | Sherry McCammon (b) (4) | 13 Oct 2020 16:53:49 |

US3742169

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:15:04

[Was the sample collected?](#)

| Audit                 | User                    | Time (GMT)           |
|-----------------------|-------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)        | 28 Oct 2020 16:00:47 |
| User entered 'No (N)' | Sherry McCammon (b) (4) | 13 Oct 2020 16:53:49 |
|                       | (b) (4)                 |                      |

US3742169

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:15:04

Collection time (00:00 - 23:59)

| Audit               | User                    | Time (GMT)           |
|---------------------|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)        | 28 Oct 2020 16:00:47 |
| User entered empty. | Sherry McCammon (b) (4) | 13 Oct 2020 16:53:49 |
|                     | (b) (4)                 |                      |



US3742169

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:15:04

[Collection date and time \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 13 Oct 2020 16:53:49 |

US3742169

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:15:04

[Is the participant continuing to the next visit?](#)

| Audit                  | User                    | Time (GMT)           |
|------------------------|-------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)        | 28 Oct 2020 16:01:00 |
| User entered 'Yes (Y)' | Sherry McCammon (b) (4) | 13 Oct 2020 16:59:48 |
|                        | (b) (4)                 |                      |

US3742169

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 11:15:04**

[Continuing Flag](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 13 Oct 2020 16:59:48 |

US3742169

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:15:04

[Was Contact Attempted?](#)

| Audit                  | User                    | Time (GMT)           |
|------------------------|-------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)        | 28 Oct 2020 15:55:42 |
| User entered 'Yes (Y)' | Sherry McCammon (b) (4) | 13 Oct 2020 17:00:41 |
|                        | (b) (4)                 |                      |

US3742169

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:15:04

Date of Contact or Contact Attempt (*dd MMM yyyy*)

| Audit                      | User                    | Time (GMT)           |
|----------------------------|-------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)        | 28 Oct 2020 15:55:42 |
| User entered '12 Oct 2020' | Sherry McCammon (b) (4) | 13 Oct 2020 17:00:41 |
|                            | (b) (4)                 |                      |

US3742169

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 11:15:04**

[Please select one status for the follow-up contact](#)

| Audit                                      | User                    | Time (GMT)           |
|--------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                        | (b) (4), (b) (6)        | 28 Oct 2020 15:55:42 |
| User entered 'Contact Made (CONTACT MADE)' | Sherry McCammon (b) (4) | 13 Oct 2020 17:00:41 |
|                                            | (b) (4)                 |                      |

US3742169

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:15:04

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit               | User                    | Time (GMT)           |
|---------------------|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)        | 28 Oct 2020 15:55:42 |
| User entered empty. | Sherry McCammon (b) (4) | 13 Oct 2020 17:00:41 |
|                     | (b) (4)                 |                      |

US3742169

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:15:04

[Is the participant continuing to the next visit?](#)

| Audit                  | User                    | Time (GMT)           |
|------------------------|-------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)        | 28 Oct 2020 15:55:53 |
| User entered 'Yes (Y)' | Sherry McCammon (b) (4) | 13 Oct 2020 17:00:47 |
|                        | (b) (4)                 |                      |



US3742169

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 11:15:04**

[Continuing Flag](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 13 Oct 2020 17:00:47 |

US3742169

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:15:04

[Was Contact Attempted?](#)

| Audit                  | User                           | Time (GMT)           |
|------------------------|--------------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)               | 28 Oct 2020 15:56:41 |
| User entered 'Yes (Y)' | Hassan Haji (b) (4)<br>(b) (4) | 19 Oct 2020 19:31:45 |

US3742169

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:15:04

Date of Contact or Contact Attempt (*dd MMM yyyy*)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 28 Oct 2020 15:56:41 |
| User entered '19 Oct 2020' | Hassan Haji (b) (4)<br>(b) (4) | 19 Oct 2020 19:31:45 |

US3742169

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 11:15:04**

[Please select one status for the follow-up contact](#)

| Audit                                      | User                           | Time (GMT)           |
|--------------------------------------------|--------------------------------|----------------------|
| DataPoint Verified.                        | (b) (4), (b) (6)               | 28 Oct 2020 15:56:41 |
| User entered 'Contact Made (CONTACT MADE)' | Hassan Haji (b) (4)<br>(b) (4) | 19 Oct 2020 19:31:45 |

US3742169

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:15:04

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 28 Oct 2020 15:56:41 |
| User entered empty. | Hassan Haji (b) (4)<br>(b) (4) | 19 Oct 2020 19:31:45 |

US3742169

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:15:04

[Is the participant continuing to the next visit?](#)

| Audit                  | User                           | Time (GMT)           |
|------------------------|--------------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)               | 28 Oct 2020 15:56:46 |
| User entered 'Yes (Y)' | Hassan Haji (b) (4)<br>(b) (4) | 19 Oct 2020 19:32:23 |

US3742169

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 11:15:04**

[Continuing Flag](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 19 Oct 2020 19:32:23 |

US3742169

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:15:04

[Was Contact Attempted?](#)

| Audit                  | User                    | Time (GMT)           |
|------------------------|-------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)        | 28 Oct 2020 15:56:53 |
| User entered 'Yes (Y)' | Sherry McCammon (b) (4) | 27 Oct 2020 16:32:06 |
|                        | (b) (4)                 |                      |



US3742169

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 11:15:04**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

| Audit                      | User                    | Time (GMT)           |
|----------------------------|-------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)        | 28 Oct 2020 15:56:53 |
| User entered '26 Oct 2020' | Sherry McCammon (b) (4) | 27 Oct 2020 16:32:06 |
|                            | (b) (4)                 |                      |

US3742169

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 11:15:04**

[Please select one status for the follow-up contact](#)

| Audit                                      | User                    | Time (GMT)           |
|--------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                        | (b) (4), (b) (6)        | 28 Oct 2020 15:56:53 |
| User entered 'Contact Made (CONTACT MADE)' | Sherry McCammon (b) (4) | 27 Oct 2020 16:32:06 |
|                                            | (b) (4)                 |                      |

US3742169

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:15:04

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit               | User                    | Time (GMT)           |
|---------------------|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)        | 28 Oct 2020 15:56:53 |
| User entered empty. | Sherry McCammon (b) (4) | 27 Oct 2020 16:32:06 |
|                     | (b) (4)                 |                      |

US3742169

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:15:04

[Is the participant continuing to the next visit?](#)

| Audit                  | User                    | Time (GMT)           |
|------------------------|-------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)        | 28 Oct 2020 15:56:58 |
| User entered 'Yes (Y)' | Sherry McCammon (b) (4) | 27 Oct 2020 16:33:02 |
|                        | (b) (4)                 |                      |

US3742169

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 11:15:04**

[Continuing Flag](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 27 Oct 2020 16:33:02 |

US3742169

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:15:04

[Was this visit performed?](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 19 Nov 2020 18:10:15 |
|                        |                  |                      |

US3742169

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:15:04

[Visit date \(dd MMM yyyy\)](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| User entered '19 Nov 2020' | (b) (4), (b) (6) | 19 Nov 2020 18:10:15 |
|                            |                  |                      |

US3742169

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:15:04

[Was visit performed at the participant's home or at the clinic?](#)

| Audit                          | User             | Time (GMT)           |
|--------------------------------|------------------|----------------------|
| User entered 'Clinic (Clinic)' | (b) (4), (b) (6) | 19 Nov 2020 18:10:15 |
|                                |                  |                      |



**US3742169**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 26 Nov 2020 11:15:04**

[Folder OID](#)

| Audit                 | User   | Time (GMT)           |
|-----------------------|--------|----------------------|
| User entered 'VISIT3' | System | 19 Nov 2020 18:10:15 |

US3742169

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:04

[Were vital signs assessed?](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| User entered 'No (N)' | (b) (4), (b) (6) | 19 Nov 2020 18:10:24 |
|                       |                  |                      |

US3742169

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:04

Date of assessment (*dd MMM yyyy*)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 19 Nov 2020 18:10:24 |
|                     |                  |                      |

US3742169

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:04

Time of assessment (00:00-23:59)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 19 Nov 2020 18:10:24 |
|                     |                  |                      |

US3742169

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:04

[Vital Signs Date and Time \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 19 Nov 2020 18:10:24 |

US3742169

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:04

Temperature (xxx.x)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 19 Nov 2020 18:10:24 |
|                     |                  |                      |

US3742169

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:04

[Route of measurement](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 19 Nov 2020 18:10:24 |
|                     |                  |                      |

US3742169

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:04

[If Other, specify](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 19 Nov 2020 18:10:24 |
|                     |                  |                      |



US3742169

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:04

Pulse (xxx)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 19 Nov 2020 18:10:24 |
|                     |                  |                      |

US3742169

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:04

[Pulse units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 19 Nov 2020 18:10:24 |

US3742169

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:04

[Respiratory Rate \(xxx\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 19 Nov 2020 18:10:24 |
|                     |                  |                      |

US3742169

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:04

[Respiratory Rate units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 19 Nov 2020 18:10:24 |

US3742169

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:04

Systolic Blood Pressure (xxx)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 19 Nov 2020 18:10:24 |
|                     |                  |                      |

US3742169

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:04

[Systolic Blood Pressure units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 19 Nov 2020 18:10:24 |

US3742169

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:04

Diastolic Blood Pressure (xxx)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 19 Nov 2020 18:10:24 |
|                     |                  |                      |

US3742169

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:04

[Diastolic Blood Pressure units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 19 Nov 2020 18:10:24 |



US3742169

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:15:04

[Was the physical examination performed?](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| User entered 'No (N)' | (b) (4), (b) (6) | 19 Nov 2020 18:11:15 |
|                       |                  |                      |

US3742169

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:15:04

Date of examination (*dd MMM yyyy*)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 19 Nov 2020 18:11:15 |
|                     |                  |                      |

US3742169

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:15:04

[Was the sample collected?](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 19 Nov 2020 18:11:25 |
|                        |                  |                      |

US3742169

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:15:04

Collection date (*dd MMM yyyy*)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| User entered '19 Nov 2020' | (b) (4), (b) (6) | 19 Nov 2020 18:11:25 |
|                            |                  |                      |

US3742169

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:15:04

Collection time (00:00-23:59)

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| User entered '12:22' | (b) (4), (b) (6) | 19 Nov 2020 18:11:25 |
|                      |                  |                      |

US3742169

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 26 Nov 2020 11:15:04**

[Collection date and time \(derived\)](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '19 Nov 2020 12:22' | System | 19 Nov 2020 18:11:25 |

US3742169

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:15:04

[Is the participant continuing to the next visit?](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 19 Nov 2020 18:15:48 |
|                        |                  |                      |

**US3742169**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 11:15:04**

[Continuing Flag](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 19 Nov 2020 18:15:48 |



US3742169

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:04

**TIMEPOINT**

| Audit                 | User   | Time (GMT)           |
|-----------------------|--------|----------------------|
| Data entry locked.    | System | 31 Aug 2020 14:08:19 |
| User entered 'Day 64' | System | 31 Aug 2020 14:08:19 |

US3742169

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-11-04T11:07:58', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'dbc3906a-9d4e-4c37-a65a-c3e935003270' | System | 04 Nov 2020 16:09:30 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                     | System | 04 Nov 2020 16:09:30 |

US3742169

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-11-04T11:08:04', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'dbc3906a-9d4e-4c37-a65a-c3e935003270' | System | 04 Nov 2020 16:09:30 |
| User entered 'No (N)'                                                                                                                                                                                                                      | System | 04 Nov 2020 16:09:30 |

US3742169

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-11-04T11:08:10', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'dbc3906a-9d4e-4c37-a65a-c3e935003270' | System | 04 Nov 2020 16:09:30 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                     | System | 04 Nov 2020 16:09:30 |

US3742169

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Fever \(Temperature  \$\geq\$  100.4°F/38°C\)](#)

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-11-04T11:09:04', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'dbc3906a-9d4e-4c37-a65a-c3e935003270' | System | 04 Nov 2020 16:09:30 |
| User entered '0'                                                                                                                                                                                                                           | System | 04 Nov 2020 16:09:30 |

**US3742169**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Chills](#)

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-11-04T11:09:04', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'dbc3906a-9d4e-4c37-a65a-c3e935003270' | System | 04 Nov 2020 16:09:30 |
| User entered '1'                                                                                                                                                                                                                           | System | 04 Nov 2020 16:09:30 |

**US3742169**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Cough](#)

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-11-04T11:09:04', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'dbc3906a-9d4e-4c37-a65a-c3e935003270' | System | 04 Nov 2020 16:09:30 |
| User entered '0'                                                                                                                                                                                                                           | System | 04 Nov 2020 16:09:30 |

**US3742169**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Shortness of breath](#)

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-11-04T11:09:04', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'dbc3906a-9d4e-4c37-a65a-c3e935003270' | System | 04 Nov 2020 16:09:30 |
| User entered '1'                                                                                                                                                                                                                           | System | 04 Nov 2020 16:09:30 |



**US3742169**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Difficulty breathing](#)

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-11-04T11:09:04', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'dbc3906a-9d4e-4c37-a65a-c3e935003270' | System | 04 Nov 2020 16:09:30 |
| User entered '0'                                                                                                                                                                                                                           | System | 04 Nov 2020 16:09:30 |

US3742169

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Fatigue](#)

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-11-04T11:09:04', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'dbc3906a-9d4e-4c37-a65a-c3e935003270' | System | 04 Nov 2020 16:09:30 |
| User entered '1'                                                                                                                                                                                                                           | System | 04 Nov 2020 16:09:30 |

US3742169

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Muscle aches](#)

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-11-04T11:09:04', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'dbc3906a-9d4e-4c37-a65a-c3e935003270' | System | 04 Nov 2020 16:09:30 |
| User entered '1'                                                                                                                                                                                                                           | System | 04 Nov 2020 16:09:30 |

**US3742169**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Body aches](#)

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-11-04T11:09:04', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'dbc3906a-9d4e-4c37-a65a-c3e935003270' | System | 04 Nov 2020 16:09:30 |
| User entered '0'                                                                                                                                                                                                                           | System | 04 Nov 2020 16:09:30 |

US3742169

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Headache](#)

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-11-04T11:09:04', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'dbc3906a-9d4e-4c37-a65a-c3e935003270' | System | 04 Nov 2020 16:09:30 |
| User entered '0'                                                                                                                                                                                                                           | System | 04 Nov 2020 16:09:30 |

**US3742169**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[New loss of taste](#)

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-11-04T11:09:04', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'dbc3906a-9d4e-4c37-a65a-c3e935003270' | System | 04 Nov 2020 16:09:30 |
| User entered '0'                                                                                                                                                                                                                           | System | 04 Nov 2020 16:09:30 |

**US3742169**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[New loss of smell](#)

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-11-04T11:09:04', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'dbc3906a-9d4e-4c37-a65a-c3e935003270' | System | 04 Nov 2020 16:09:30 |
| User entered '0'                                                                                                                                                                                                                           | System | 04 Nov 2020 16:09:30 |

**US3742169**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Sore throat](#)

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-11-04T11:09:04', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'dbc3906a-9d4e-4c37-a65a-c3e935003270' | System | 04 Nov 2020 16:09:30 |
| User entered '0'                                                                                                                                                                                                                           | System | 04 Nov 2020 16:09:30 |



US3742169

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Congestion](#)

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-11-04T11:09:04', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'dbc3906a-9d4e-4c37-a65a-c3e935003270' | System | 04 Nov 2020 16:09:30 |
| User entered '1'                                                                                                                                                                                                                           | System | 04 Nov 2020 16:09:30 |

**US3742169**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Runny nose](#)

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-11-04T11:09:04', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'dbc3906a-9d4e-4c37-a65a-c3e935003270' | System | 04 Nov 2020 16:09:30 |
| User entered '0'                                                                                                                                                                                                                           | System | 04 Nov 2020 16:09:30 |

US3742169

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Nausea](#)

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-11-04T11:09:04', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'dbc3906a-9d4e-4c37-a65a-c3e935003270' | System | 04 Nov 2020 16:09:30 |
| User entered '0'                                                                                                                                                                                                                           | System | 04 Nov 2020 16:09:30 |

**US3742169**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Vomiting](#)

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-11-04T11:09:04', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'dbc3906a-9d4e-4c37-a65a-c3e935003270' | System | 04 Nov 2020 16:09:30 |
| User entered '0'                                                                                                                                                                                                                           | System | 04 Nov 2020 16:09:30 |

**US3742169**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Diarrhea](#)

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-11-04T11:09:04', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'dbc3906a-9d4e-4c37-a65a-c3e935003270' | System | 04 Nov 2020 16:09:30 |
| User entered '0'                                                                                                                                                                                                                           | System | 04 Nov 2020 16:09:30 |

**US3742169**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-11-04T11:09:07', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'dbc3906a-9d4e-4c37-a65a-c3e935003270' | System | 04 Nov 2020 16:09:30 |
| User entered 'I confirm I have read this message and will call the study clinic immediately (9)'                                                                                                                                           | System | 04 Nov 2020 16:09:30 |

US3742169

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-11-04T11:09:15', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'dbc3906a-9d4e-4c37-a65a-c3e935003270' | System | 04 Nov 2020 16:09:30 |
| User entered 'No (N)'                                                                                                                                                                                                                      | System | 04 Nov 2020 16:09:30 |

**US3742169**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Date and time of submission](#)

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-11-04T11:09:21', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'dbc3906a-9d4e-4c37-a65a-c3e935003270' | System | 04 Nov 2020 16:09:30 |
| User entered '04 Nov 2020 11:09:21'                                                                                                                                                                                                        | System | 04 Nov 2020 16:09:30 |



US3742169

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| Data entry locked.               | System | 31 Aug 2020 14:08:19 |
| User entered '31 Oct 2020 00:01' | System | 31 Aug 2020 14:08:19 |

US3742169

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| Data entry locked.               | System | 31 Aug 2020 14:08:19 |
| User entered '04 Nov 2020 23:59' | System | 31 Aug 2020 14:08:19 |

US3742169

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:04

**TIMEPOINT**

| Audit                 | User   | Time (GMT)           |
|-----------------------|--------|----------------------|
| Data entry locked.    | System | 31 Aug 2020 14:08:19 |
| User entered 'Day 71' | System | 31 Aug 2020 14:08:19 |

US3742169

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-11-09T12:36:34', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: '50263d56-511d-4c80-a0a2-b67169483d31' | System | 09 Nov 2020 17:37:16 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                     | System | 09 Nov 2020 17:37:16 |

US3742169

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-11-09T12:36:43', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: '50263d56-511d-4c80-a0a2-b67169483d31' | System | 09 Nov 2020 17:37:16 |
| User entered 'No (N)'                                                                                                                                                                                                                      | System | 09 Nov 2020 17:37:16 |

US3742169

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-11-09T12:36:50', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: '50263d56-511d-4c80-a0a2-b67169483d31' | System | 09 Nov 2020 17:37:16 |
| User entered 'No (N)'                                                                                                                                                                                                                      | System | 09 Nov 2020 17:37:16 |

US3742169

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-11-09T12:36:57', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: '50263d56-511d-4c80-a0a2-b67169483d31' | System | 09 Nov 2020 17:37:16 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                     | System | 09 Nov 2020 17:37:16 |

**US3742169**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-11-09T12:37:02', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: '50263d56-511d-4c80-a0a2-b67169483d31' | System | 09 Nov 2020 17:37:16 |
| User entered 'I confirm I have read this message and will call the study clinic immediately (9)'                                                                                                                                           | System | 09 Nov 2020 17:37:16 |



**US3742169**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Date and time of submission](#)

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-11-09T12:37:05', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: '50263d56-511d-4c80-a0a2-b67169483d31' | System | 09 Nov 2020 17:37:16 |
| User entered '09 Nov 2020 12:37:05'                                                                                                                                                                                                        | System | 09 Nov 2020 17:37:16 |

US3742169

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| Data entry locked.               | System | 31 Aug 2020 14:08:19 |
| User entered '07 Nov 2020 00:01' | System | 31 Aug 2020 14:08:19 |

US3742169

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| Data entry locked.               | System | 31 Aug 2020 14:08:19 |
| User entered '11 Nov 2020 23:59' | System | 31 Aug 2020 14:08:19 |

US3742169

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:04

**TIMEPOINT**

| Audit                 | User   | Time (GMT)           |
|-----------------------|--------|----------------------|
| Data entry locked.    | System | 31 Aug 2020 14:08:19 |
| User entered 'Day 78' | System | 31 Aug 2020 14:08:19 |

US3742169

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-11-18T19:37:19', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: '6459a4cc-7be2-4c34-b2d7-a377191a4e06' | System | 19 Nov 2020 00:37:29 |
| User entered 'No (N)'                                                                                                                                                                                                                      | System | 19 Nov 2020 00:37:29 |

US3742169

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-11-18T19:37:22', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: '6459a4cc-7be2-4c34-b2d7-a377191a4e06' | System | 19 Nov 2020 00:37:29 |
| User entered 'No (N)'                                                                                                                                                                                                                      | System | 19 Nov 2020 00:37:29 |

**US3742169**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Date and time of submission](#)

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-11-18T19:37:26', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: '6459a4cc-7be2-4c34-b2d7-a377191a4e06' | System | 19 Nov 2020 00:37:29 |
| User entered '18 Nov 2020 19:37:26'                                                                                                                                                                                                        | System | 19 Nov 2020 00:37:29 |

US3742169

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| Data entry locked.               | System | 31 Aug 2020 14:08:19 |
| User entered '14 Nov 2020 00:01' | System | 31 Aug 2020 14:08:19 |



US3742169

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| Data entry locked.               | System | 31 Aug 2020 14:08:19 |
| User entered '18 Nov 2020 23:59' | System | 31 Aug 2020 14:08:19 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

**TIMEPOINT**

| Audit                                    | User   | Time (GMT)           |
|------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.    | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered 'Day 61' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '28 Oct 2020 00:01' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '01 Nov 2020 23:59' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

**TIMEPOINT**

| Audit                                    | User   | Time (GMT)           |
|------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.    | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered 'Day 68' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '04 Nov 2020 00:01' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '08 Nov 2020 23:59' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

**TIMEPOINT**

| Audit                                    | User   | Time (GMT)           |
|------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.    | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered 'Day 75' | System | 19 Nov 2020 20:42:28 |



**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '11 Nov 2020 00:01' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '15 Nov 2020 23:59' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

**TIMEPOINT**

| Audit                                    | User   | Time (GMT)           |
|------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.    | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered 'Day 82' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-11-22T23:05:57', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: '7d631077-9363-468a-9b04-b12ab8ba2768' | System | 23 Nov 2020 04:06:11 |
| User entered 'No (N)'                                                                                                                                                                                                                      | System | 23 Nov 2020 04:06:11 |

US3742169

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-11-22T23:06:04', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: '7d631077-9363-468a-9b04-b12ab8ba2768' | System | 23 Nov 2020 04:06:11 |
| User entered 'No (N)'                                                                                                                                                                                                                      | System | 23 Nov 2020 04:06:11 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Date and time of submission](#)

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-11-22T23:06:07', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: '7d631077-9363-468a-9b04-b12ab8ba2768' | System | 23 Nov 2020 04:06:11 |
| User entered '22 Nov 2020 23:06:07'                                                                                                                                                                                                        | System | 23 Nov 2020 04:06:11 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '18 Nov 2020 00:01' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '22 Nov 2020 23:59' | System | 19 Nov 2020 20:42:28 |



**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

**TIMEPOINT**

| Audit                                    | User   | Time (GMT)           |
|------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.    | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered 'Day 89' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '25 Nov 2020 00:01' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '29 Nov 2020 23:59' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

**TIMEPOINT**

| Audit                                    | User   | Time (GMT)           |
|------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.    | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered 'Day 96' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '02 Dec 2020 00:01' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '06 Dec 2020 23:59' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered 'Day 103' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '09 Dec 2020 00:01' | System | 19 Nov 2020 20:42:28 |



**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '13 Dec 2020 23:59' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered 'Day 110' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '16 Dec 2020 00:01' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '20 Dec 2020 23:59' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered 'Day 117' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '23 Dec 2020 00:01' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '27 Dec 2020 23:59' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered 'Day 124' | System | 19 Nov 2020 20:42:28 |



**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '30 Dec 2020 00:01' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '03 Jan 2021 23:59' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered 'Day 131' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '06 Jan 2021 00:01' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '10 Jan 2021 23:59' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered 'Day 138' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '13 Jan 2021 00:01' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '17 Jan 2021 23:59' | System | 19 Nov 2020 20:42:28 |



**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered 'Day 145' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '20 Jan 2021 00:01' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '24 Jan 2021 23:59' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered 'Day 152' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '27 Jan 2021 00:01' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '31 Jan 2021 23:59' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered 'Day 159' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '03 Feb 2021 00:01' | System | 19 Nov 2020 20:42:28 |



**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '07 Feb 2021 23:59' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered 'Day 166' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '10 Feb 2021 00:01' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '14 Feb 2021 23:59' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered 'Day 173' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '17 Feb 2021 00:01' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '21 Feb 2021 23:59' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered 'Day 180' | System | 19 Nov 2020 20:42:28 |



**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '24 Feb 2021 00:01' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '28 Feb 2021 23:59' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered 'Day 187' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '03 Mar 2021 00:01' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '07 Mar 2021 23:59' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered 'Day 194' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '10 Mar 2021 00:01' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '14 Mar 2021 23:59' | System | 19 Nov 2020 20:42:28 |



**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered 'Day 201' | System | 19 Nov 2020 20:42:28 |

US3742169

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '17 Mar 2021 00:01' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '21 Mar 2021 23:59' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered 'Day 208' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '24 Mar 2021 00:01' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '28 Mar 2021 23:59' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered 'Day 215' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '31 Mar 2021 00:01' | System | 19 Nov 2020 20:42:28 |



**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '04 Apr 2021 23:59' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered 'Day 222' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '07 Apr 2021 00:01' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '11 Apr 2021 23:59' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered 'Day 229' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '14 Apr 2021 00:01' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '18 Apr 2021 23:59' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered 'Day 236' | System | 19 Nov 2020 20:42:28 |



**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '21 Apr 2021 00:01' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '25 Apr 2021 23:59' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered 'Day 243' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '28 Apr 2021 00:01' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '02 May 2021 23:59' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered 'Day 250' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '05 May 2021 00:01' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '09 May 2021 23:59' | System | 19 Nov 2020 20:42:28 |



**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered 'Day 257' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '12 May 2021 00:01' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '16 May 2021 23:59' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered 'Day 264' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '19 May 2021 00:01' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '23 May 2021 23:59' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered 'Day 271' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '26 May 2021 00:01' | System | 19 Nov 2020 20:42:28 |



**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '30 May 2021 23:59' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered 'Day 278' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '02 Jun 2021 00:01' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '06 Jun 2021 23:59' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered 'Day 285' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '09 Jun 2021 00:01' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '13 Jun 2021 23:59' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered 'Day 292' | System | 19 Nov 2020 20:42:28 |



**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '16 Jun 2021 00:01' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '20 Jun 2021 23:59' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered 'Day 299' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '23 Jun 2021 00:01' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '27 Jun 2021 23:59' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered 'Day 306' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '30 Jun 2021 00:01' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '04 Jul 2021 23:59' | System | 19 Nov 2020 20:42:28 |



**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered 'Day 313' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '07 Jul 2021 00:01' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '11 Jul 2021 23:59' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered 'Day 320' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '14 Jul 2021 00:01' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '18 Jul 2021 23:59' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered 'Day 327' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '21 Jul 2021 00:01' | System | 19 Nov 2020 20:42:28 |



**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '25 Jul 2021 23:59' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered 'Day 334' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '28 Jul 2021 00:01' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '01 Aug 2021 23:59' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered 'Day 341' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '04 Aug 2021 00:01' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '08 Aug 2021 23:59' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered 'Day 348' | System | 19 Nov 2020 20:42:28 |



**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '11 Aug 2021 00:01' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '15 Aug 2021 23:59' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered 'Day 355' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '18 Aug 2021 00:01' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '22 Aug 2021 23:59' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered 'Day 362' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '25 Aug 2021 00:01' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '29 Aug 2021 23:59' | System | 19 Nov 2020 20:42:28 |



**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered 'Day 369' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '01 Sep 2021 00:01' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '05 Sep 2021 23:59' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered 'Day 376' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '08 Sep 2021 00:01' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '12 Sep 2021 23:59' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered 'Day 383' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '15 Sep 2021 00:01' | System | 19 Nov 2020 20:42:28 |



**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '19 Sep 2021 23:59' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered 'Day 390' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '22 Sep 2021 00:01' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '26 Sep 2021 23:59' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered 'Day 397' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '29 Sep 2021 00:01' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '03 Oct 2021 23:59' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered 'Day 404' | System | 19 Nov 2020 20:42:28 |



**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '06 Oct 2021 00:01' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '10 Oct 2021 23:59' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered 'Day 411' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '13 Oct 2021 00:01' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '17 Oct 2021 23:59' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered 'Day 418' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '20 Oct 2021 00:01' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '24 Oct 2021 23:59' | System | 19 Nov 2020 20:42:28 |



**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered 'Day 425' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '27 Oct 2021 00:01' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '31 Oct 2021 23:59' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered 'Day 432' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '03 Nov 2021 00:01' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '07 Nov 2021 23:59' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered 'Day 439' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '10 Nov 2021 00:01' | System | 19 Nov 2020 20:42:28 |



**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '14 Nov 2021 23:59' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered 'Day 446' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '17 Nov 2021 00:01' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '21 Nov 2021 23:59' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered 'Day 453' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '24 Nov 2021 00:01' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '28 Nov 2021 23:59' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered 'Day 460' | System | 19 Nov 2020 20:42:28 |



US3742169

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '01 Dec 2021 00:01' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '05 Dec 2021 23:59' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered 'Day 467' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '08 Dec 2021 00:01' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '12 Dec 2021 23:59' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered 'Day 474' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '15 Dec 2021 00:01' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '19 Dec 2021 23:59' | System | 19 Nov 2020 20:42:28 |



**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered 'Day 481' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '22 Dec 2021 00:01' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '26 Dec 2021 23:59' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered 'Day 488' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '29 Dec 2021 00:01' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '02 Jan 2022 23:59' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered 'Day 495' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '05 Jan 2022 00:01' | System | 19 Nov 2020 20:42:28 |



**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '09 Jan 2022 23:59' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered 'Day 502' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '12 Jan 2022 00:01' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '16 Jan 2022 23:59' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered 'Day 509' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '19 Jan 2022 00:01' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '23 Jan 2022 23:59' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered 'Day 516' | System | 19 Nov 2020 20:42:28 |



**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '26 Jan 2022 00:01' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '30 Jan 2022 23:59' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered 'Day 523' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '02 Feb 2022 00:01' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '06 Feb 2022 23:59' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered 'Day 530' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '09 Feb 2022 00:01' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '13 Feb 2022 23:59' | System | 19 Nov 2020 20:42:28 |



**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered 'Day 537' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '16 Feb 2022 00:01' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '20 Feb 2022 23:59' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered 'Day 544' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '23 Feb 2022 00:01' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '27 Feb 2022 23:59' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered 'Day 551' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '02 Mar 2022 00:01' | System | 19 Nov 2020 20:42:28 |



**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '06 Mar 2022 23:59' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered 'Day 558' | System | 19 Nov 2020 20:42:28 |

US3742169

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '09 Mar 2022 00:01' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '13 Mar 2022 23:59' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered 'Day 565' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '16 Mar 2022 00:01' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '20 Mar 2022 23:59' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered 'Day 572' | System | 19 Nov 2020 20:42:28 |



**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '23 Mar 2022 00:01' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '27 Mar 2022 23:59' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered 'Day 579' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '30 Mar 2022 00:01' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '03 Apr 2022 23:59' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered 'Day 586' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '06 Apr 2022 00:01' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '10 Apr 2022 23:59' | System | 19 Nov 2020 20:42:28 |



**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered 'Day 593' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '13 Apr 2022 00:01' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '17 Apr 2022 23:59' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered 'Day 600' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '20 Apr 2022 00:01' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '24 Apr 2022 23:59' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered 'Day 607' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '27 Apr 2022 00:01' | System | 19 Nov 2020 20:42:28 |



**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '01 May 2022 23:59' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered 'Day 614' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '04 May 2022 00:01' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '08 May 2022 23:59' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered 'Day 621' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '11 May 2022 00:01' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '15 May 2022 23:59' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered 'Day 628' | System | 19 Nov 2020 20:42:28 |



**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '18 May 2022 00:01' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '22 May 2022 23:59' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered 'Day 635' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '25 May 2022 00:01' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '29 May 2022 23:59' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered 'Day 642' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '01 Jun 2022 00:01' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '05 Jun 2022 23:59' | System | 19 Nov 2020 20:42:28 |



**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered 'Day 649' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '08 Jun 2022 00:01' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '12 Jun 2022 23:59' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered 'Day 656' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '15 Jun 2022 00:01' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '19 Jun 2022 23:59' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered 'Day 663' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '22 Jun 2022 00:01' | System | 19 Nov 2020 20:42:28 |



**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '26 Jun 2022 23:59' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered 'Day 670' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '29 Jun 2022 00:01' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '03 Jul 2022 23:59' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered 'Day 677' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '06 Jul 2022 00:01' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '10 Jul 2022 23:59' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered 'Day 684' | System | 19 Nov 2020 20:42:28 |



**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '13 Jul 2022 00:01' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '17 Jul 2022 23:59' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered 'Day 691' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '20 Jul 2022 00:01' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '24 Jul 2022 23:59' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered 'Day 698' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '27 Jul 2022 00:01' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '31 Jul 2022 23:59' | System | 19 Nov 2020 20:42:28 |



**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered 'Day 705' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '03 Aug 2022 00:01' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '07 Aug 2022 23:59' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered 'Day 712' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '10 Aug 2022 00:01' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '14 Aug 2022 23:59' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered 'Day 719' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '17 Aug 2022 00:01' | System | 19 Nov 2020 20:42:28 |



**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '21 Aug 2022 23:59' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered 'Day 726' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '24 Aug 2022 00:01' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '28 Aug 2022 23:59' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered 'Day 733' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '31 Aug 2022 00:01' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '04 Sep 2022 23:59' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered 'Day 740' | System | 19 Nov 2020 20:42:28 |



**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '07 Sep 2022 00:01' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '11 Sep 2022 23:59' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered 'Day 747' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '14 Sep 2022 00:01' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '18 Sep 2022 23:59' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered 'Day 754' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '21 Sep 2022 00:01' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '25 Sep 2022 23:59' | System | 19 Nov 2020 20:42:28 |



**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered 'Day 761' | System | 19 Nov 2020 20:42:28 |

US3742169

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '28 Sep 2022 00:01' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '02 Oct 2022 23:59' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered 'Day 768' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '05 Oct 2022 00:01' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '09 Oct 2022 23:59' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered 'Day 775' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '12 Oct 2022 00:01' | System | 19 Nov 2020 20:42:28 |



**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '16 Oct 2022 23:59' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered 'Day 782' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '19 Oct 2022 00:01' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '23 Oct 2022 23:59' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered 'Day 789' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '26 Oct 2022 00:01' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '30 Oct 2022 23:59' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered 'Day 796' | System | 19 Nov 2020 20:42:28 |



**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '02 Nov 2022 00:01' | System | 19 Nov 2020 20:42:28 |

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:15:04**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:42:28 |
| Amendment Manager: User entered '06 Nov 2022 23:59' | System | 19 Nov 2020 20:42:28 |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 11:15:04

[Date of Contact](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 10 Nov 2020 17:36:31 |
| User entered '06 Nov 2020' | (b) (4), (b) (6) | 10 Nov 2020 17:21:14 |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 11:15:04

[Time of Contact](#)

| Audit                                                                                  | User             | Time (GMT)           |
|----------------------------------------------------------------------------------------|------------------|----------------------|
| DataPoint Verified.                                                                    | (b) (4), (b) (6) | 10 Nov 2020 17:36:31 |
| User closed query 'Data is required. Please complete.' (Site from System).             | System           | 10 Nov 2020 17:22:00 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System           | 10 Nov 2020 17:22:00 |
| User entered '12:20' reason for change: Data Entry Error                               | (b) (4), (b) (6) | 10 Nov 2020 17:22:00 |
| User opened query 'Data is required. Please complete.' (Site from System).             | System           | 10 Nov 2020 17:21:14 |
| User entered empty.                                                                    | (b) (4), (b) (6) | 10 Nov 2020 17:21:14 |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 11:15:04

[Date and Time of Contact \(derived\)](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '06 Nov 2020 12:20' | System | 10 Nov 2020 17:22:00 |
| User entered empty.              | System | 10 Nov 2020 17:21:14 |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 11:15:04

[Type of Contact](#)

| Audit                                                                      | User             | Time (GMT)           |
|----------------------------------------------------------------------------|------------------|----------------------|
| DataPoint Verified.                                                        | (b) (4), (b) (6) | 10 Nov 2020 17:36:31 |
| User entered 'Clinical Visit - Unscheduled (Clinical Visit - Unscheduled)' | (b) (4), (b) (6) | 10 Nov 2020 17:21:14 |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 11:15:04

[Has the subject reported symptoms of SARS-COV-2?](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 10 Nov 2020 17:36:31 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 10 Nov 2020 17:21:14 |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:15:04

[Symptom Day](#)

| Audit                        | User             | Time (GMT)           |
|------------------------------|------------------|----------------------|
| User entered 'Day 1 (Day 1)' | (b) (4), (b) (6) | 10 Nov 2020 17:25:05 |
|                              |                  |                      |



US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:15:04

[Date](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| DataPoint Un-verified.                                         | Sherry McCammon (b) (4) | 19 Nov 2020 19:48:24 |
| User entered '30 Oct 2020' reason for change: Data Entry Error | (b) (4)                 |                      |
|                                                                | Sherry McCammon (b) (4) | 19 Nov 2020 19:48:24 |
| DataPoint Verified.                                            | (b) (4)                 |                      |
|                                                                | (b) (4), (b) (6)        | 10 Nov 2020 17:37:26 |
| User entered '06 Nov 2020'                                     | (b) (4), (b) (6)        | 10 Nov 2020 17:25:05 |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:15:04

[Assessment Not Done](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 10 Nov 2020 17:37:26 |
| User entered '0'    | (b) (4), (b) (6) | 10 Nov 2020 17:25:05 |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:15:04

[O2 Saturation](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 10 Nov 2020 17:37:26 |
| User entered empty. | (b) (4), (b) (6) | 10 Nov 2020 17:25:05 |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:15:04

[O2 Saturation Units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 10 Nov 2020 17:25:05 |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:15:04

[Temperature](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 10 Nov 2020 17:37:26 |
| User entered empty. | (b) (4), (b) (6) | 10 Nov 2020 17:25:05 |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:15:04

[Chills](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| DataPoint Un-verified.                                         | Sherry McCammon (b) (4) | 19 Nov 2020 19:53:50 |
| User entered 'Mild (Mild)' reason for change: Data Entry Error | (b) (4)                 |                      |
|                                                                | Sherry McCammon (b) (4) | 19 Nov 2020 19:53:50 |
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 10 Nov 2020 17:37:26 |
| User entered 'None (None)'                                     | (b) (4), (b) (6)        | 10 Nov 2020 17:25:05 |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:15:04

[Cough](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 10 Nov 2020 17:37:26 |
| User entered 'None (None)' | (b) (4), (b) (6) | 10 Nov 2020 17:25:05 |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:15:04

[Shortness of Breath](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 10 Nov 2020 17:37:26 |
| User entered 'None (None)' | (b) (4), (b) (6) | 10 Nov 2020 17:25:05 |



US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:15:04

[Difficulty Breathing](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 10 Nov 2020 17:37:26 |
| User entered 'None (None)' | (b) (4), (b) (6) | 10 Nov 2020 17:25:05 |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:15:04

[Fatigue](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 10 Nov 2020 17:37:26 |
| User entered 'None (None)' | (b) (4), (b) (6) | 10 Nov 2020 17:25:05 |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:15:04

[Muscle Aches \(Myalgia\)](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| DataPoint Un-verified.                                         | Sherry McCammon (b) (4) | 19 Nov 2020 19:55:43 |
| User entered 'None (None)' reason for change: Data Entry Error | (b) (4)                 |                      |
|                                                                | Sherry McCammon (b) (4) | 19 Nov 2020 19:55:43 |
| DataPoint Verified.                                            | (b) (4)                 |                      |
|                                                                | (b) (4), (b) (6)        | 10 Nov 2020 17:37:26 |
| User entered 'Mild (Mild)'                                     | (b) (4), (b) (6)        | 10 Nov 2020 17:25:05 |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:15:04

[Body Aches](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 10 Nov 2020 17:37:26 |
| User entered 'None (None)' | (b) (4), (b) (6) | 10 Nov 2020 17:25:05 |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:15:04

[Headache](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 10 Nov 2020 17:37:26 |
| User entered 'None (None)' | (b) (4), (b) (6) | 10 Nov 2020 17:25:05 |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:15:04

[New Loss of Taste](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 10 Nov 2020 17:37:26 |
| User entered 'None (None)' | (b) (4), (b) (6) | 10 Nov 2020 17:25:05 |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:15:04

[New Loss of Smell](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 10 Nov 2020 17:37:26 |
| User entered 'None (None)' | (b) (4), (b) (6) | 10 Nov 2020 17:25:05 |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:15:04

[Nasal Congestion](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 10 Nov 2020 17:37:26 |
| User entered 'None (None)' | (b) (4), (b) (6) | 10 Nov 2020 17:25:05 |



US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:15:04

[Runny Nose \(Rhinorrhea\)](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 10 Nov 2020 17:37:26 |
| User entered 'None (None)' | (b) (4), (b) (6) | 10 Nov 2020 17:25:05 |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:15:04

[Nausea](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 10 Nov 2020 17:37:26 |
| User entered 'None (None)' | (b) (4), (b) (6) | 10 Nov 2020 17:25:05 |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:15:04

[Vomiting](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 10 Nov 2020 17:37:26 |
| User entered 'None (None)' | (b) (4), (b) (6) | 10 Nov 2020 17:25:05 |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:15:04

[Diarrhea](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 10 Nov 2020 17:37:26 |
| User entered 'None (None)' | (b) (4), (b) (6) | 10 Nov 2020 17:25:05 |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:15:04

[Sore Throat](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 10 Nov 2020 17:37:26 |
| User entered 'None (None)' | (b) (4), (b) (6) | 10 Nov 2020 17:25:05 |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:15:04

[Symptom Day](#)

| Audit                        | User                    | Time (GMT)           |
|------------------------------|-------------------------|----------------------|
| User entered 'Day 2 (Day 2)' | Sherry McCammon (b) (4) | 19 Nov 2020 19:48:39 |
|                              | (b) (4)                 |                      |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:15:04

[Date](#)

| Audit                      | User                    | Time (GMT)           |
|----------------------------|-------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered '31 Oct 2020' | Sherry McCammon (b) (4) | 19 Nov 2020 19:48:39 |
|                            | (b) (4)                 |                      |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:15:04

[Assessment Not Done](#)

| Audit               | User                    | Time (GMT)           |
|---------------------|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered '0'    | Sherry McCammon (b) (4) | 19 Nov 2020 19:48:39 |
|                     | (b) (4)                 |                      |



US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:15:04

[O2 Saturation](#)

| Audit               | User                    | Time (GMT)           |
|---------------------|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered empty. | Sherry McCammon (b) (4) | 19 Nov 2020 19:48:39 |
|                     | (b) (4)                 |                      |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:15:04

[O2 Saturation Units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 19 Nov 2020 19:48:39 |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:15:04

[Temperature](#)

| Audit               | User                    | Time (GMT)           |
|---------------------|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered empty. | Sherry McCammon (b) (4) | 19 Nov 2020 19:48:39 |
|                     | (b) (4)                 |                      |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:15:04

[Chills](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'Mild (Mild)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 19:53:50 |
| User entered empty.                                            | Sherry McCammon (b) (4) | 19 Nov 2020 19:48:39 |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:15:04

[Cough](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'None (None)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 20:01:58 |
| User entered empty.                                            | Sherry McCammon (b) (4) | 19 Nov 2020 19:48:39 |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:15:04

[Shortness of Breath](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'None (None)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 20:01:58 |
| User entered empty.                                            | Sherry McCammon (b) (4) | 19 Nov 2020 19:48:39 |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:15:04

[Difficulty Breathing](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'None (None)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 20:03:06 |
| User entered empty.                                            | Sherry McCammon (b) (4) | 19 Nov 2020 19:48:39 |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:15:04

[Fatigue](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'None (None)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 20:03:06 |
| User entered empty.                                            | Sherry McCammon (b) (4) | 19 Nov 2020 19:48:39 |



US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:15:04

[Muscle Aches \(Myalgia\)](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'Mild (Mild)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 19:55:43 |
| User entered empty.                                            | Sherry McCammon (b) (4) | 19 Nov 2020 19:48:39 |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:15:04

[Body Aches](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'None (None)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 20:05:04 |
| User entered empty.                                            | Sherry McCammon (b) (4) | 19 Nov 2020 19:48:39 |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:15:04

[Headache](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'Mild (Mild)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 19:57:50 |
| User entered empty.                                            | Sherry McCammon (b) (4) | 19 Nov 2020 19:48:39 |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:15:04

[New Loss of Taste](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'None (None)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 20:06:29 |
| User entered empty.                                            | Sherry McCammon (b) (4) | 19 Nov 2020 19:48:39 |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:15:04

[New Loss of Smell](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'None (None)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 20:06:29 |
| User entered empty.                                            | Sherry McCammon (b) (4) | 19 Nov 2020 19:48:39 |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:15:04

[Nasal Congestion](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'None (None)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 20:08:11 |
| User entered empty.                                            | (b) (4)                 |                      |
|                                                                | Sherry McCammon (b) (4) | 19 Nov 2020 19:48:39 |
|                                                                | (b) (4)                 |                      |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:15:04

[Runny Nose \(Rhinorrhea\)](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'None (None)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 20:08:11 |
| User entered empty.                                            | (b) (4)                 |                      |
|                                                                | Sherry McCammon (b) (4) | 19 Nov 2020 19:48:39 |
|                                                                | (b) (4)                 |                      |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:15:04

[Nausea](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'None (None)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 20:09:01 |
| User entered empty.                                            | (b) (4)                 |                      |
|                                                                | Sherry McCammon (b) (4) | 19 Nov 2020 19:48:39 |
|                                                                | (b) (4)                 |                      |



US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:15:04

[Vomiting](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'None (None)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 20:10:25 |
| User entered empty.                                            | Sherry McCammon (b) (4) | 19 Nov 2020 19:48:39 |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:15:04

[Diarrhea](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'None (None)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 20:11:26 |
| User entered empty.                                            | Sherry McCammon (b) (4) | 19 Nov 2020 19:48:39 |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:15:04

[Sore Throat](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'None (None)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 20:12:16 |
| User entered empty.                                            | Sherry McCammon (b) (4) | 19 Nov 2020 19:48:39 |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:15:04

[Symptom Day](#)

| Audit                        | User                    | Time (GMT)           |
|------------------------------|-------------------------|----------------------|
| User entered 'Day 3 (Day 3)' | Sherry McCammon (b) (4) | 19 Nov 2020 19:49:09 |
|                              | (b) (4)                 |                      |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:15:04

[Date](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered '01 Nov 2020' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 19:53:12 |
| User entered '1 Nov 2020'                                      | Sherry McCammon (b) (4) | 19 Nov 2020 19:49:09 |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:15:04

[Assessment Not Done](#)

| Audit               | User                    | Time (GMT)           |
|---------------------|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered '0'    | Sherry McCammon (b) (4) | 19 Nov 2020 19:49:09 |
|                     | (b) (4)                 |                      |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:15:04

[O2 Saturation](#)

| Audit               | User                    | Time (GMT)           |
|---------------------|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered empty. | Sherry McCammon (b) (4) | 19 Nov 2020 19:49:09 |
|                     | (b) (4)                 |                      |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:15:04

[O2 Saturation Units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 19 Nov 2020 19:49:09 |



US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:15:04

[Temperature](#)

| Audit               | User                    | Time (GMT)           |
|---------------------|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered empty. | Sherry McCammon (b) (4) | 19 Nov 2020 19:49:09 |
|                     | (b) (4)                 |                      |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:15:04

[Chills](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'Mild (Mild)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 19:53:50 |
| User entered empty.                                            | Sherry McCammon (b) (4) | 19 Nov 2020 19:49:09 |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:15:04

[Cough](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'None (None)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 20:01:58 |
| User entered empty.                                            | Sherry McCammon (b) (4) | 19 Nov 2020 19:49:09 |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:15:04

[Shortness of Breath](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'None (None)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 20:03:06 |
| User entered empty.                                            | Sherry McCammon (b) (4) | 19 Nov 2020 19:49:09 |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:15:04

[Difficulty Breathing](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'None (None)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 20:03:06 |
| User entered empty.                                            | Sherry McCammon (b) (4) | 19 Nov 2020 19:49:09 |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:15:04

[Fatigue](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'None (None)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 20:03:06 |
| User entered empty.                                            | Sherry McCammon (b) (4) | 19 Nov 2020 19:49:09 |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:15:04

[Muscle Aches \(Myalgia\)](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'None (None)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 20:05:04 |
| User entered empty.                                            | Sherry McCammon (b) (4) | 19 Nov 2020 19:49:09 |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:15:04

[Body Aches](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'None (None)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 20:05:04 |
| User entered empty.                                            | Sherry McCammon (b) (4) | 19 Nov 2020 19:49:09 |



US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:15:04

[Headache](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'Mild (Mild)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 19:57:50 |
| User entered empty.                                            | Sherry McCammon (b) (4) | 19 Nov 2020 19:49:09 |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:15:04

[New Loss of Taste](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'None (None)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 20:06:29 |
| User entered empty.                                            | Sherry McCammon (b) (4) | 19 Nov 2020 19:49:09 |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:15:04

[New Loss of Smell](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'None (None)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 20:06:29 |
| User entered empty.                                            | Sherry McCammon (b) (4) | 19 Nov 2020 19:49:09 |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:15:04

[Nasal Congestion](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'None (None)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 20:08:11 |
| User entered empty.                                            | Sherry McCammon (b) (4) | 19 Nov 2020 19:49:09 |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:15:04

[Runny Nose \(Rhinorrhea\)](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'None (None)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 20:08:11 |
| User entered empty.                                            | (b) (4)                 |                      |
|                                                                | Sherry McCammon (b) (4) | 19 Nov 2020 19:49:09 |
|                                                                | (b) (4)                 |                      |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:15:04

[Nausea](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'None (None)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 20:09:01 |
| User entered empty.                                            | (b) (4)                 |                      |
|                                                                | Sherry McCammon (b) (4) | 19 Nov 2020 19:49:09 |
|                                                                | (b) (4)                 |                      |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:15:04

[Vomiting](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'None (None)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 20:10:25 |
| User entered empty.                                            | Sherry McCammon (b) (4) | 19 Nov 2020 19:49:09 |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:15:04

[Diarrhea](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'None (None)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 20:11:26 |
| User entered empty.                                            | Sherry McCammon (b) (4) | 19 Nov 2020 19:49:09 |



US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:15:04

[Sore Throat](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'None (None)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 20:12:16 |
| User entered empty.                                            | Sherry McCammon (b) (4) | 19 Nov 2020 19:49:09 |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:15:04

[Symptom Day](#)

| Audit                        | User                    | Time (GMT)           |
|------------------------------|-------------------------|----------------------|
| User entered 'Day 4 (Day 4)' | Sherry McCammon (b) (4) | 19 Nov 2020 19:49:33 |
|                              | (b) (4)                 |                      |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:15:04

[Date](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered '02 Nov 2020' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 19:53:12 |
| User entered '2 Nov 2020'                                      | Sherry McCammon (b) (4) | 19 Nov 2020 19:49:33 |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:15:04

[Assessment Not Done](#)

| Audit               | User                    | Time (GMT)           |
|---------------------|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered '0'    | Sherry McCammon (b) (4) | 19 Nov 2020 19:49:33 |
|                     | (b) (4)                 |                      |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:15:04

[O2 Saturation](#)

| Audit               | User                    | Time (GMT)           |
|---------------------|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered empty. | Sherry McCammon (b) (4) | 19 Nov 2020 19:49:33 |
|                     | (b) (4)                 |                      |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:15:04

[O2 Saturation Units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 19 Nov 2020 19:49:33 |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:15:04

[Temperature](#)

| Audit               | User                    | Time (GMT)           |
|---------------------|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered empty. | Sherry McCammon (b) (4) | 19 Nov 2020 19:49:33 |
|                     | (b) (4)                 |                      |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:15:04

[Chills](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'Mild (Mild)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 19:53:50 |
| User entered empty.                                            | Sherry McCammon (b) (4) | 19 Nov 2020 19:49:33 |



US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:15:04

[Cough](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'None (None)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 20:01:58 |
| User entered empty.                                            | Sherry McCammon (b) (4) | 19 Nov 2020 19:49:33 |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:15:04

[Shortness of Breath](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'None (None)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 20:03:06 |
| User entered empty.                                            | Sherry McCammon (b) (4) | 19 Nov 2020 19:49:33 |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:15:04

[Difficulty Breathing](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'None (None)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 20:03:06 |
| User entered empty.                                            | Sherry McCammon (b) (4) | 19 Nov 2020 19:49:33 |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:15:04

[Fatigue](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'None (None)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 20:03:06 |
| User entered empty.                                            | Sherry McCammon (b) (4) | 19 Nov 2020 19:49:33 |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:15:04

[Muscle Aches \(Myalgia\)](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'None (None)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 20:05:04 |
| User entered empty.                                            | Sherry McCammon (b) (4) | 19 Nov 2020 19:49:33 |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:15:04

[Body Aches](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'None (None)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 20:05:04 |
| User entered empty.                                            | Sherry McCammon (b) (4) | 19 Nov 2020 19:49:33 |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:15:04

[Headache](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'Mild (Mild)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 19:57:50 |
| User entered empty.                                            | Sherry McCammon (b) (4) | 19 Nov 2020 19:49:33 |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:15:04

[New Loss of Taste](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'None (None)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 20:06:29 |
| User entered empty.                                            | Sherry McCammon (b) (4) | 19 Nov 2020 19:49:33 |



US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:15:04

[New Loss of Smell](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'None (None)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 20:06:29 |
| User entered empty.                                            | Sherry McCammon (b) (4) | 19 Nov 2020 19:49:33 |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:15:04

[Nasal Congestion](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'None (None)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 20:08:11 |
| User entered empty.                                            | (b) (4)                 |                      |
|                                                                | Sherry McCammon (b) (4) | 19 Nov 2020 19:49:33 |
|                                                                | (b) (4)                 |                      |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:15:04

[Runny Nose \(Rhinorrhea\)](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'None (None)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 20:08:11 |
| User entered empty.                                            | (b) (4)                 |                      |
|                                                                | Sherry McCammon (b) (4) | 19 Nov 2020 19:49:33 |
|                                                                | (b) (4)                 |                      |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:15:04

[Nausea](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'None (None)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 20:09:01 |
| User entered empty.                                            | (b) (4)                 |                      |
|                                                                | Sherry McCammon (b) (4) | 19 Nov 2020 19:49:33 |
|                                                                | (b) (4)                 |                      |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:15:04

[Vomiting](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'None (None)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 20:10:25 |
| User entered empty.                                            | Sherry McCammon (b) (4) | 19 Nov 2020 19:49:33 |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:15:04

[Diarrhea](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'None (None)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 20:11:26 |
| User entered empty.                                            | Sherry McCammon (b) (4) | 19 Nov 2020 19:49:33 |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:15:04

[Sore Throat](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'None (None)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 20:12:16 |
| User entered empty.                                            | Sherry McCammon (b) (4) | 19 Nov 2020 19:49:33 |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:15:04

[Symptom Day](#)

| Audit                        | User                    | Time (GMT)           |
|------------------------------|-------------------------|----------------------|
| User entered 'Day 5 (Day 5)' | Sherry McCammon (b) (4) | 19 Nov 2020 19:49:44 |
|                              | (b) (4)                 |                      |



US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:15:04

[Date](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered '03 Nov 2020' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 19:53:12 |
| User entered '3 Nov 2020'                                      | Sherry McCammon (b) (4) | 19 Nov 2020 19:49:44 |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:15:04

[Assessment Not Done](#)

| Audit               | User                    | Time (GMT)           |
|---------------------|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered '0'    | Sherry McCammon (b) (4) | 19 Nov 2020 19:49:44 |
|                     | (b) (4)                 |                      |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:15:04

[O2 Saturation](#)

| Audit               | User                    | Time (GMT)           |
|---------------------|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered empty. | Sherry McCammon (b) (4) | 19 Nov 2020 19:49:44 |
|                     | (b) (4)                 |                      |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:15:04

[O2 Saturation Units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 19 Nov 2020 19:49:44 |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:15:04

[Temperature](#)

| Audit               | User                    | Time (GMT)           |
|---------------------|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered empty. | Sherry McCammon (b) (4) | 19 Nov 2020 19:49:44 |
|                     | (b) (4)                 |                      |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:15:04

[Chills](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'Mild (Mild)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 19:53:50 |
| User entered empty.                                            | Sherry McCammon (b) (4) | 19 Nov 2020 19:49:44 |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:15:04

[Cough](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'None (None)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 20:01:58 |
| User entered empty.                                            | Sherry McCammon (b) (4) | 19 Nov 2020 19:49:44 |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:15:04

[Shortness of Breath](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'None (None)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 20:03:06 |
| User entered empty.                                            | Sherry McCammon (b) (4) | 19 Nov 2020 19:49:44 |



US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:15:04

[Difficulty Breathing](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'None (None)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 20:03:06 |
| User entered empty.                                            | Sherry McCammon (b) (4) | 19 Nov 2020 19:49:44 |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:15:04

[Fatigue](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'None (None)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 20:03:06 |
| User entered empty.                                            | Sherry McCammon (b) (4) | 19 Nov 2020 19:49:44 |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:15:04

[Muscle Aches \(Myalgia\)](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'None (None)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 20:05:04 |
| User entered empty.                                            | Sherry McCammon (b) (4) | 19 Nov 2020 19:49:44 |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:15:04

[Body Aches](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'None (None)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 20:05:04 |
| User entered empty.                                            | Sherry McCammon (b) (4) | 19 Nov 2020 19:49:44 |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:15:04

[Headache](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'Mild (Mild)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 19:57:50 |
| User entered empty.                                            | Sherry McCammon (b) (4) | 19 Nov 2020 19:49:44 |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:15:04

[New Loss of Taste](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'None (None)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 20:06:29 |
| User entered empty.                                            | Sherry McCammon (b) (4) | 19 Nov 2020 19:49:44 |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:15:04

[New Loss of Smell](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'None (None)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 20:06:29 |
| User entered empty.                                            | Sherry McCammon (b) (4) | 19 Nov 2020 19:49:44 |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:15:04

[Nasal Congestion](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'None (None)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 20:08:11 |
| User entered empty.                                            | Sherry McCammon (b) (4) | 19 Nov 2020 19:49:44 |



US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:15:04

[Runny Nose \(Rhinorrhea\)](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'None (None)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 20:08:11 |
| User entered empty.                                            | (b) (4)                 |                      |
|                                                                | Sherry McCammon (b) (4) | 19 Nov 2020 19:49:44 |
|                                                                | (b) (4)                 |                      |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:15:04

[Nausea](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'None (None)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 20:09:01 |
| User entered empty.                                            | (b) (4)                 |                      |
|                                                                | Sherry McCammon (b) (4) | 19 Nov 2020 19:49:44 |
|                                                                | (b) (4)                 |                      |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:15:04

[Vomiting](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'None (None)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 20:10:25 |
| User entered empty.                                            | Sherry McCammon (b) (4) | 19 Nov 2020 19:49:44 |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:15:04

[Diarrhea](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'None (None)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 20:11:26 |
| User entered empty.                                            | Sherry McCammon (b) (4) | 19 Nov 2020 19:49:44 |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:15:04

[Sore Throat](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'None (None)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 20:12:16 |
| User entered empty.                                            | Sherry McCammon (b) (4) | 19 Nov 2020 19:49:44 |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:15:04

[Symptom Day](#)

| Audit                        | User                    | Time (GMT)           |
|------------------------------|-------------------------|----------------------|
| User entered 'Day 6 (Day 6)' | Sherry McCammon (b) (4) | 19 Nov 2020 19:49:54 |
|                              | (b) (4)                 |                      |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:15:04

[Date](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered '04 Nov 2020' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 19:53:12 |
| User entered '4 Nov 2020'                                      | Sherry McCammon (b) (4) | 19 Nov 2020 19:49:54 |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:15:04

[Assessment Not Done](#)

| Audit               | User                    | Time (GMT)           |
|---------------------|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered '0'    | Sherry McCammon (b) (4) | 19 Nov 2020 19:49:54 |
|                     | (b) (4)                 |                      |



US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:15:04

[O2 Saturation](#)

| Audit               | User                    | Time (GMT)           |
|---------------------|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered empty. | Sherry McCammon (b) (4) | 19 Nov 2020 19:49:54 |
|                     | (b) (4)                 |                      |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:15:04

[O2 Saturation Units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 19 Nov 2020 19:49:54 |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:15:04

[Temperature](#)

| Audit               | User                    | Time (GMT)           |
|---------------------|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered empty. | Sherry McCammon (b) (4) | 19 Nov 2020 19:49:54 |
|                     | (b) (4)                 |                      |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:15:04

[Chills](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'Mild (Mild)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 19:53:50 |
| User entered empty.                                            | Sherry McCammon (b) (4) | 19 Nov 2020 19:49:54 |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:15:04

[Cough](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'None (None)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 20:01:58 |
| User entered empty.                                            | Sherry McCammon (b) (4) | 19 Nov 2020 19:49:54 |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:15:04

[Shortness of Breath](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'None (None)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 20:03:06 |
| User entered empty.                                            | Sherry McCammon (b) (4) | 19 Nov 2020 19:49:54 |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:15:04

[Difficulty Breathing](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'None (None)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 20:03:06 |
| User entered empty.                                            | Sherry McCammon (b) (4) | 19 Nov 2020 19:49:54 |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:15:04

[Fatigue](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'None (None)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 20:03:06 |
| User entered empty.                                            | Sherry McCammon (b) (4) | 19 Nov 2020 19:49:54 |



US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:15:04

[Muscle Aches \(Myalgia\)](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'None (None)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 20:05:04 |
| User entered empty.                                            | Sherry McCammon (b) (4) | 19 Nov 2020 19:49:54 |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:15:04

[Body Aches](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'None (None)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 20:05:04 |
| User entered empty.                                            | Sherry McCammon (b) (4) | 19 Nov 2020 19:49:54 |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:15:04

[Headache](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'Mild (Mild)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 19:57:50 |
| User entered empty.                                            | Sherry McCammon (b) (4) | 19 Nov 2020 19:49:54 |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:15:04

[New Loss of Taste](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'None (None)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 20:06:29 |
| User entered empty.                                            | Sherry McCammon (b) (4) | 19 Nov 2020 19:49:54 |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:15:04

[New Loss of Smell](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'None (None)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 20:06:29 |
| User entered empty.                                            | Sherry McCammon (b) (4) | 19 Nov 2020 19:49:54 |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:15:04

[Nasal Congestion](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'None (None)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 20:08:11 |
| User entered empty.                                            | (b) (4)                 |                      |
|                                                                | Sherry McCammon (b) (4) | 19 Nov 2020 19:49:54 |
|                                                                | (b) (4)                 |                      |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:15:04

[Runny Nose \(Rhinorrhea\)](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'None (None)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 20:08:11 |
| User entered empty.                                            | (b) (4)                 |                      |
|                                                                | Sherry McCammon (b) (4) | 19 Nov 2020 19:49:54 |
|                                                                | (b) (4)                 |                      |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:15:04

[Nausea](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'None (None)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 20:09:01 |
| User entered empty.                                            | (b) (4)                 |                      |
|                                                                | Sherry McCammon (b) (4) | 19 Nov 2020 19:49:54 |
|                                                                | (b) (4)                 |                      |



US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:15:04

[Vomiting](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'None (None)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 20:10:25 |
| User entered empty.                                            | Sherry McCammon (b) (4) | 19 Nov 2020 19:49:54 |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:15:04

[Diarrhea](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'None (None)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 20:11:26 |
| User entered empty.                                            | Sherry McCammon (b) (4) | 19 Nov 2020 19:49:54 |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:15:04

[Sore Throat](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'None (None)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 20:12:16 |
| User entered empty.                                            | Sherry McCammon (b) (4) | 19 Nov 2020 19:49:54 |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:15:04

[Symptom Day](#)

| Audit                        | User                    | Time (GMT)           |
|------------------------------|-------------------------|----------------------|
| User entered 'Day 7 (Day 7)' | Sherry McCammon (b) (4) | 19 Nov 2020 19:50:06 |
|                              | (b) (4)                 |                      |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:15:04

[Date](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered '05 Nov 2020' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 19:53:12 |
| User entered '5 Nov 2020'                                      | Sherry McCammon (b) (4) | 19 Nov 2020 19:50:06 |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:15:04

[Assessment Not Done](#)

| Audit               | User                    | Time (GMT)           |
|---------------------|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered '0'    | Sherry McCammon (b) (4) | 19 Nov 2020 19:50:06 |
|                     | (b) (4)                 |                      |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:15:04

[O2 Saturation](#)

| Audit               | User                    | Time (GMT)           |
|---------------------|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered empty. | Sherry McCammon (b) (4) | 19 Nov 2020 19:50:06 |
|                     | (b) (4)                 |                      |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:15:04

[O2 Saturation Units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 19 Nov 2020 19:50:06 |



US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:15:04

[Temperature](#)

| Audit               | User                    | Time (GMT)           |
|---------------------|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered empty. | Sherry McCammon (b) (4) | 19 Nov 2020 19:50:06 |
|                     | (b) (4)                 |                      |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:15:04

[Chills](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'None (None)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 20:01:58 |
| User entered empty.                                            | Sherry McCammon (b) (4) | 19 Nov 2020 19:50:06 |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:15:04

[Cough](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'None (None)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 20:01:58 |
| User entered empty.                                            | (b) (4)                 |                      |
|                                                                | Sherry McCammon (b) (4) | 19 Nov 2020 19:50:06 |
|                                                                | (b) (4)                 |                      |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:15:04

[Shortness of Breath](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'None (None)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 20:03:06 |
| User entered empty.                                            | Sherry McCammon (b) (4) | 19 Nov 2020 19:50:06 |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:15:04

[Difficulty Breathing](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'None (None)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 20:03:06 |
| User entered empty.                                            | Sherry McCammon (b) (4) | 19 Nov 2020 19:50:06 |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:15:04

[Fatigue](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'None (None)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 20:03:06 |
| User entered empty.                                            | Sherry McCammon (b) (4) | 19 Nov 2020 19:50:06 |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:15:04

[Muscle Aches \(Myalgia\)](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'None (None)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 20:05:04 |
| User entered empty.                                            | Sherry McCammon (b) (4) | 19 Nov 2020 19:50:06 |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:15:04

[Body Aches](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'None (None)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 20:05:04 |
| User entered empty.                                            | Sherry McCammon (b) (4) | 19 Nov 2020 19:50:06 |



US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:15:04

[Headache](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'Mild (Mild)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 19:57:50 |
| User entered empty.                                            | Sherry McCammon (b) (4) | 19 Nov 2020 19:50:06 |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:15:04

[New Loss of Taste](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'None (None)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 20:06:29 |
| User entered empty.                                            | Sherry McCammon (b) (4) | 19 Nov 2020 19:50:06 |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:15:04

[New Loss of Smell](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'None (None)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 20:06:29 |
| User entered empty.                                            | Sherry McCammon (b) (4) | 19 Nov 2020 19:50:06 |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:15:04

[Nasal Congestion](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'None (None)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 20:08:11 |
| User entered empty.                                            | (b) (4)                 |                      |
|                                                                | Sherry McCammon (b) (4) | 19 Nov 2020 19:50:06 |
|                                                                | (b) (4)                 |                      |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:15:04

[Runny Nose \(Rhinorrhea\)](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'None (None)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 20:08:11 |
| User entered empty.                                            | (b) (4)                 |                      |
|                                                                | Sherry McCammon (b) (4) | 19 Nov 2020 19:50:06 |
|                                                                | (b) (4)                 |                      |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:15:04

[Nausea](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'None (None)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 20:09:01 |
| User entered empty.                                            | (b) (4)                 |                      |
|                                                                | Sherry McCammon (b) (4) | 19 Nov 2020 19:50:06 |
|                                                                | (b) (4)                 |                      |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:15:04

[Vomiting](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'None (None)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 20:10:25 |
| User entered empty.                                            | Sherry McCammon (b) (4) | 19 Nov 2020 19:50:06 |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:15:04

[Diarrhea](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'None (None)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 20:11:26 |
| User entered empty.                                            | Sherry McCammon (b) (4) | 19 Nov 2020 19:50:06 |



US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:15:04

[Sore Throat](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'None (None)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 20:12:16 |
| User entered empty.                                            | Sherry McCammon (b) (4) | 19 Nov 2020 19:50:06 |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:15:04

[Symptom Day](#)

| Audit                        | User                    | Time (GMT)           |
|------------------------------|-------------------------|----------------------|
| User entered 'Day 8 (Day 8)' | Sherry McCammon (b) (4) | 19 Nov 2020 19:50:23 |
|                              | (b) (4)                 |                      |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:15:04

[Date](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered '06 Nov 2020' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 19:53:12 |
| User entered '6 Nov 2020'                                      | Sherry McCammon (b) (4) | 19 Nov 2020 19:50:23 |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:15:04

[Assessment Not Done](#)

| Audit               | User                    | Time (GMT)           |
|---------------------|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered '0'    | Sherry McCammon (b) (4) | 19 Nov 2020 19:50:23 |
|                     | (b) (4)                 |                      |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:15:04

[O2 Saturation](#)

| Audit                                                 | User                    | Time (GMT)           |
|-------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                   | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered '97' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 20:13:33 |
| User entered empty.                                   | Sherry McCammon (b) (4) | 19 Nov 2020 19:50:23 |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:15:04

[O2 Saturation Units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '%'    | System | 19 Nov 2020 20:13:33 |
| User entered empty. | System | 19 Nov 2020 19:50:23 |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:15:04

[Temperature](#)

| Audit                                                     | User                    | Time (GMT)           |
|-----------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                       | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered '98.0' F reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 20:15:12 |
| User entered empty.                                       | Sherry McCammon (b) (4) | 19 Nov 2020 19:50:23 |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:15:04

[Chills](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'None (None)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 20:01:58 |
| User entered empty.                                            | Sherry McCammon (b) (4) | 19 Nov 2020 19:50:23 |



US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:15:04

[Cough](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'None (None)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 20:01:58 |
| User entered empty.                                            | Sherry McCammon (b) (4) | 19 Nov 2020 19:50:23 |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:15:04

[Shortness of Breath](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'None (None)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 20:03:06 |
| User entered empty.                                            | Sherry McCammon (b) (4) | 19 Nov 2020 19:50:23 |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:15:04

[Difficulty Breathing](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'None (None)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 20:04:09 |
| User entered empty.                                            | Sherry McCammon (b) (4) | 19 Nov 2020 19:50:23 |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:15:04

[Fatigue](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'None (None)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 20:04:09 |
| User entered empty.                                            | Sherry McCammon (b) (4) | 19 Nov 2020 19:50:23 |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:15:04

[Muscle Aches \(Myalgia\)](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'Mild (Mild)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 19:55:43 |
| User entered empty.                                            | Sherry McCammon (b) (4) | 19 Nov 2020 19:50:23 |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:15:04

[Body Aches](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'None (None)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 20:05:04 |
| User entered empty.                                            | Sherry McCammon (b) (4) | 19 Nov 2020 19:50:23 |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:15:04

[Headache](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'None (None)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 19:57:50 |
| User entered empty.                                            | (b) (4)                 |                      |
|                                                                | Sherry McCammon (b) (4) | 19 Nov 2020 19:50:23 |
|                                                                | (b) (4)                 |                      |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:15:04

[New Loss of Taste](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'None (None)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 20:06:29 |
| User entered empty.                                            | Sherry McCammon (b) (4) | 19 Nov 2020 19:50:23 |



US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:15:04

[New Loss of Smell](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'None (None)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 20:06:29 |
| User entered empty.                                            | Sherry McCammon (b) (4) | 19 Nov 2020 19:50:23 |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:15:04

[Nasal Congestion](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'None (None)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 20:08:11 |
| User entered empty.                                            | (b) (4)                 |                      |
|                                                                | Sherry McCammon (b) (4) | 19 Nov 2020 19:50:23 |
|                                                                | (b) (4)                 |                      |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:15:04

[Runny Nose \(Rhinorrhea\)](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'None (None)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 20:08:11 |
| User entered empty.                                            | (b) (4)                 |                      |
|                                                                | Sherry McCammon (b) (4) | 19 Nov 2020 19:50:23 |
|                                                                | (b) (4)                 |                      |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:15:04

[Nausea](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'None (None)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 20:09:01 |
| User entered empty.                                            | (b) (4)                 |                      |
|                                                                | Sherry McCammon (b) (4) | 19 Nov 2020 19:50:23 |
|                                                                | (b) (4)                 |                      |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:15:04

[Vomiting](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'None (None)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 20:10:25 |
| User entered empty.                                            | Sherry McCammon (b) (4) | 19 Nov 2020 19:50:23 |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:15:04

[Diarrhea](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'None (None)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 20:11:26 |
| User entered empty.                                            | Sherry McCammon (b) (4) | 19 Nov 2020 19:50:23 |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:15:04

[Sore Throat](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'None (None)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 20:12:16 |
| User entered empty.                                            | Sherry McCammon (b) (4) | 19 Nov 2020 19:50:23 |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:15:04

[Symptom Day](#)

| Audit                        | User                    | Time (GMT)           |
|------------------------------|-------------------------|----------------------|
| User entered 'Day 9 (Day 9)' | Sherry McCammon (b) (4) | 19 Nov 2020 19:50:37 |
|                              | (b) (4)                 |                      |



US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:15:04

[Date](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered '07 Nov 2020' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 19:53:12 |
| User entered '7 Nov 2020'                                      | Sherry McCammon (b) (4) | 19 Nov 2020 19:50:37 |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:15:04

[Assessment Not Done](#)

| Audit               | User                    | Time (GMT)           |
|---------------------|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered '0'    | Sherry McCammon (b) (4) | 19 Nov 2020 19:50:37 |
|                     | (b) (4)                 |                      |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:15:04

[O2 Saturation](#)

| Audit                                                 | User                    | Time (GMT)           |
|-------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                   | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered '98' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 20:13:33 |
| User entered empty.                                   | Sherry McCammon (b) (4) | 19 Nov 2020 19:50:37 |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:15:04

[O2 Saturation Units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '%'    | System | 19 Nov 2020 20:13:33 |
| User entered empty. | System | 19 Nov 2020 19:50:37 |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:15:04

[Temperature](#)

| Audit                                                     | User                    | Time (GMT)           |
|-----------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                       | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered '98.2' F reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 20:15:12 |
| User entered empty.                                       | Sherry McCammon (b) (4) | 19 Nov 2020 19:50:37 |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:15:04

[Chills](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'None (None)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 20:01:58 |
| User entered empty.                                            | Sherry McCammon (b) (4) | 19 Nov 2020 19:50:37 |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:15:04

[Cough](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'None (None)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 20:01:58 |
| User entered empty.                                            | Sherry McCammon (b) (4) | 19 Nov 2020 19:50:37 |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:15:04

[Shortness of Breath](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'None (None)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 20:03:06 |
| User entered empty.                                            | Sherry McCammon (b) (4) | 19 Nov 2020 19:50:37 |



US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:15:04

[Difficulty Breathing](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'None (None)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 20:04:09 |
| User entered empty.                                            | Sherry McCammon (b) (4) | 19 Nov 2020 19:50:37 |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:15:04

[Fatigue](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'None (None)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 20:04:09 |
| User entered empty.                                            | (b) (4)                 |                      |
|                                                                | Sherry McCammon (b) (4) | 19 Nov 2020 19:50:37 |
|                                                                | (b) (4)                 |                      |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:15:04

[Muscle Aches \(Myalgia\)](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'Mild (Mild)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 19:55:43 |
| User entered empty.                                            | Sherry McCammon (b) (4) | 19 Nov 2020 19:50:37 |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:15:04

[Body Aches](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'Mild (Mild)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 19:59:18 |
| User entered empty.                                            | Sherry McCammon (b) (4) | 19 Nov 2020 19:50:37 |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:15:04

[Headache](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'Mild (Mild)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 19:57:50 |
| User entered empty.                                            | Sherry McCammon (b) (4) | 19 Nov 2020 19:50:37 |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:15:04

[New Loss of Taste](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'None (None)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 20:06:29 |
| User entered empty.                                            | Sherry McCammon (b) (4) | 19 Nov 2020 19:50:37 |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:15:04

[New Loss of Smell](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'None (None)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 20:06:29 |
| User entered empty.                                            | Sherry McCammon (b) (4) | 19 Nov 2020 19:50:37 |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:15:04

[Nasal Congestion](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'None (None)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 20:08:11 |
| User entered empty.                                            | (b) (4)                 |                      |
|                                                                | Sherry McCammon (b) (4) | 19 Nov 2020 19:50:37 |
|                                                                | (b) (4)                 |                      |



US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:15:04

[Runny Nose \(Rhinorrhea\)](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'None (None)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 20:08:11 |
| User entered empty.                                            | (b) (4)                 |                      |
|                                                                | Sherry McCammon (b) (4) | 19 Nov 2020 19:50:37 |
|                                                                | (b) (4)                 |                      |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:15:04

[Nausea](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'None (None)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 20:09:01 |
| User entered empty.                                            | (b) (4)                 |                      |
|                                                                | Sherry McCammon (b) (4) | 19 Nov 2020 19:50:37 |
|                                                                | (b) (4)                 |                      |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:15:04

[Vomiting](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'None (None)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 20:10:25 |
| User entered empty.                                            | Sherry McCammon (b) (4) | 19 Nov 2020 19:50:37 |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:15:04

[Diarrhea](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'None (None)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 20:11:26 |
| User entered empty.                                            | Sherry McCammon (b) (4) | 19 Nov 2020 19:50:37 |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:15:04

[Sore Throat](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'None (None)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 20:12:16 |
| User entered empty.                                            | Sherry McCammon (b) (4) | 19 Nov 2020 19:50:37 |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:15:04

[Symptom Day](#)

| Audit                                             | User            | Time (GMT)                   |
|---------------------------------------------------|-----------------|------------------------------|
| User entered 'Day 10 (Day 10)' reason for change: | Sherry McCammon | (b) (4) 19 Nov 2020 19:51:41 |
| Data Entry Error                                  | (b) (4)         |                              |
| User entered empty.                               | Sherry McCammon | (b) (4) 19 Nov 2020 19:50:58 |
|                                                   | (b) (4)         |                              |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:15:04

[Date](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered '08 Nov 2020' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 19:53:12 |
| User entered '8 Nov 2020'                                      | Sherry McCammon (b) (4) | 19 Nov 2020 19:50:58 |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:15:04

[Assessment Not Done](#)

| Audit               | User                    | Time (GMT)           |
|---------------------|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered '0'    | Sherry McCammon (b) (4) | 19 Nov 2020 19:50:58 |
|                     | (b) (4)                 |                      |



US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:15:04

[O2 Saturation](#)

| Audit                                                 | User                    | Time (GMT)           |
|-------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                   | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered '94' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 20:13:33 |
| User entered empty.                                   | (b) (4)                 |                      |
|                                                       | Sherry McCammon (b) (4) | 19 Nov 2020 19:50:58 |
|                                                       | (b) (4)                 |                      |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:15:04

[O2 Saturation Units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '%'    | System | 19 Nov 2020 20:13:33 |
| User entered empty. | System | 19 Nov 2020 19:50:58 |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:15:04

[Temperature](#)

| Audit                                                     | User                    | Time (GMT)           |
|-----------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                       | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered '98.6' F reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 20:15:12 |
| User entered empty.                                       | Sherry McCammon (b) (4) | 19 Nov 2020 19:50:58 |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:15:04

[Chills](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'None (None)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 20:01:58 |
| User entered empty.                                            | (b) (4)                 |                      |
|                                                                | Sherry McCammon (b) (4) | 19 Nov 2020 19:50:58 |
|                                                                | (b) (4)                 |                      |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:15:04

[Cough](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'None (None)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 20:01:58 |
| User entered empty.                                            | (b) (4)                 |                      |
|                                                                | Sherry McCammon (b) (4) | 19 Nov 2020 19:50:58 |
|                                                                | (b) (4)                 |                      |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:15:04

[Shortness of Breath](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'None (None)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 20:03:06 |
| User entered empty.                                            | (b) (4)                 |                      |
|                                                                | Sherry McCammon (b) (4) | 19 Nov 2020 19:50:58 |
|                                                                | (b) (4)                 |                      |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:15:04

[Difficulty Breathing](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'None (None)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 20:04:09 |
| User entered empty.                                            | Sherry McCammon (b) (4) | 19 Nov 2020 19:50:58 |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:15:04

[Fatigue](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'None (None)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 20:04:09 |
| User entered empty.                                            | (b) (4)                 |                      |
|                                                                | Sherry McCammon (b) (4) | 19 Nov 2020 19:50:58 |
|                                                                | (b) (4)                 |                      |



US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:15:04

[Muscle Aches \(Myalgia\)](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'Mild (Mild)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 19:55:43 |
| User entered empty.                                            | Sherry McCammon (b) (4) | 19 Nov 2020 19:50:58 |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:15:04

[Body Aches](#)

| Audit                                                                  | User                    | Time (GMT)           |
|------------------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                                    | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'Moderate (Moderate)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 19:59:18 |
| User entered empty.                                                    | (b) (4)                 |                      |
|                                                                        | Sherry McCammon (b) (4) | 19 Nov 2020 19:50:58 |
|                                                                        | (b) (4)                 |                      |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:15:04

[Headache](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'Mild (Mild)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 19:57:50 |
| User entered empty.                                            | (b) (4)                 |                      |
|                                                                | Sherry McCammon (b) (4) | 19 Nov 2020 19:50:58 |
|                                                                | (b) (4)                 |                      |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:15:04

[New Loss of Taste](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'None (None)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 20:06:29 |
| User entered empty.                                            | Sherry McCammon (b) (4) | 19 Nov 2020 19:50:58 |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:15:04

[New Loss of Smell](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'None (None)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 20:06:29 |
| User entered empty.                                            | Sherry McCammon (b) (4) | 19 Nov 2020 19:50:58 |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:15:04

[Nasal Congestion](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'None (None)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 20:08:11 |
| User entered empty.                                            | (b) (4)                 |                      |
|                                                                | Sherry McCammon (b) (4) | 19 Nov 2020 19:50:58 |
|                                                                | (b) (4)                 |                      |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:15:04

[Runny Nose \(Rhinorrhea\)](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'None (None)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 20:08:11 |
| User entered empty.                                            | (b) (4)                 |                      |
|                                                                | Sherry McCammon (b) (4) | 19 Nov 2020 19:50:58 |
|                                                                | (b) (4)                 |                      |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:15:04

[Nausea](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'None (None)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 20:09:01 |
| User entered empty.                                            | (b) (4)                 |                      |
|                                                                | Sherry McCammon (b) (4) | 19 Nov 2020 19:50:58 |
|                                                                | (b) (4)                 |                      |



US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:15:04

[Vomiting](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'None (None)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 20:10:25 |
| User entered empty.                                            | Sherry McCammon (b) (4) | 19 Nov 2020 19:50:58 |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:15:04

[Diarrhea](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'None (None)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 20:11:26 |
| User entered empty.                                            | Sherry McCammon (b) (4) | 19 Nov 2020 19:50:58 |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:15:04

[Sore Throat](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'None (None)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 20:12:16 |
| User entered empty.                                            | Sherry McCammon (b) (4) | 19 Nov 2020 19:50:58 |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:15:04

[Symptom Day](#)

| Audit                          | User                    | Time (GMT)           |
|--------------------------------|-------------------------|----------------------|
| User entered 'Day 11 (Day 11)' | Sherry McCammon (b) (4) | 19 Nov 2020 19:51:41 |
|                                | (b) (4)                 |                      |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:15:04

[Date](#)

| Audit                      | User                    | Time (GMT)           |
|----------------------------|-------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered '09 Nov 2020' | Sherry McCammon (b) (4) | 19 Nov 2020 19:51:41 |
|                            | (b) (4)                 |                      |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:15:04

[Assessment Not Done](#)

| Audit               | User                    | Time (GMT)           |
|---------------------|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered '0'    | Sherry McCammon (b) (4) | 19 Nov 2020 19:51:41 |
|                     | (b) (4)                 |                      |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:15:04

[O2 Saturation](#)

| Audit                                                 | User                    | Time (GMT)           |
|-------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                   | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered '98' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 20:13:33 |
| User entered empty.                                   | (b) (4)                 |                      |
|                                                       | Sherry McCammon (b) (4) | 19 Nov 2020 19:51:41 |
|                                                       | (b) (4)                 |                      |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:15:04

[O2 Saturation Units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '%'    | System | 19 Nov 2020 20:13:33 |
| User entered empty. | System | 19 Nov 2020 19:51:41 |



US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:15:04

[Temperature](#)

| Audit                                                     | User                    | Time (GMT)           |
|-----------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                       | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered '98.1' F reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 20:15:12 |
| User entered empty.                                       | Sherry McCammon (b) (4) | 19 Nov 2020 19:51:41 |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:15:04

[Chills](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'None (None)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 20:01:58 |
| User entered empty.                                            | (b) (4)                 |                      |
|                                                                | Sherry McCammon (b) (4) | 19 Nov 2020 19:51:41 |
|                                                                | (b) (4)                 |                      |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:15:04

[Cough](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'None (None)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 20:01:58 |
| User entered empty.                                            | (b) (4)                 |                      |
|                                                                | Sherry McCammon (b) (4) | 19 Nov 2020 19:51:41 |
|                                                                | (b) (4)                 |                      |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:15:04

[Shortness of Breath](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'None (None)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 20:03:06 |
| User entered empty.                                            | Sherry McCammon (b) (4) | 19 Nov 2020 19:51:41 |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:15:04

[Difficulty Breathing](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'None (None)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 20:04:09 |
| User entered empty.                                            | Sherry McCammon (b) (4) | 19 Nov 2020 19:51:41 |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:15:04

[Fatigue](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'None (None)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 20:04:09 |
| User entered empty.                                            | (b) (4)                 |                      |
|                                                                | Sherry McCammon (b) (4) | 19 Nov 2020 19:51:41 |
|                                                                | (b) (4)                 |                      |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:15:04

[Muscle Aches \(Myalgia\)](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'Mild (Mild)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 19:55:43 |
| User entered empty.                                            | Sherry McCammon (b) (4) | 19 Nov 2020 19:51:41 |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:15:04

[Body Aches](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'Mild (Mild)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 19:59:18 |
| User entered empty.                                            | Sherry McCammon (b) (4) | 19 Nov 2020 19:51:41 |



US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:15:04

[Headache](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'Mild (Mild)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 19:57:50 |
| User entered empty.                                            | (b) (4)                 |                      |
|                                                                | Sherry McCammon (b) (4) | 19 Nov 2020 19:51:41 |
|                                                                | (b) (4)                 |                      |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:15:04

[New Loss of Taste](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'None (None)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 20:06:29 |
| User entered empty.                                            | Sherry McCammon (b) (4) | 19 Nov 2020 19:51:41 |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:15:04

[New Loss of Smell](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'None (None)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 20:06:29 |
| User entered empty.                                            | Sherry McCammon (b) (4) | 19 Nov 2020 19:51:41 |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:15:04

[Nasal Congestion](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'None (None)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 20:08:11 |
| User entered empty.                                            | (b) (4)                 |                      |
|                                                                | Sherry McCammon (b) (4) | 19 Nov 2020 19:51:41 |
|                                                                | (b) (4)                 |                      |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:15:04

[Runny Nose \(Rhinorrhea\)](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'None (None)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 20:08:11 |
| User entered empty.                                            | (b) (4)                 |                      |
|                                                                | Sherry McCammon (b) (4) | 19 Nov 2020 19:51:41 |
|                                                                | (b) (4)                 |                      |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:15:04

[Nausea](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'None (None)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 20:09:01 |
| User entered empty.                                            | (b) (4)                 |                      |
|                                                                | Sherry McCammon (b) (4) | 19 Nov 2020 19:51:41 |
|                                                                | (b) (4)                 |                      |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:15:04

[Vomiting](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'None (None)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 20:10:25 |
| User entered empty.                                            | Sherry McCammon (b) (4) | 19 Nov 2020 19:51:41 |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:15:04

[Diarrhea](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'None (None)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 20:11:26 |
| User entered empty.                                            | Sherry McCammon (b) (4) | 19 Nov 2020 19:51:41 |



US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:15:04

[Sore Throat](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'None (None)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 20:12:16 |
| User entered empty.                                            | Sherry McCammon (b) (4) | 19 Nov 2020 19:51:41 |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:15:04

[Symptom Day](#)

| Audit                          | User                    | Time (GMT)           |
|--------------------------------|-------------------------|----------------------|
| User entered 'Day 12 (Day 12)' | Sherry McCammon (b) (4) | 19 Nov 2020 19:51:51 |
|                                | (b) (4)                 |                      |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:15:04

[Date](#)

| Audit                      | User                    | Time (GMT)           |
|----------------------------|-------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered '10 Nov 2020' | Sherry McCammon (b) (4) | 19 Nov 2020 19:51:51 |
|                            | (b) (4)                 |                      |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:15:04

[Assessment Not Done](#)

| Audit               | User                    | Time (GMT)           |
|---------------------|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered '0'    | Sherry McCammon (b) (4) | 19 Nov 2020 19:51:51 |
|                     | (b) (4)                 |                      |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:15:04

[O2 Saturation](#)

| Audit                                                 | User                    | Time (GMT)           |
|-------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                   | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered '97' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 20:13:33 |
| User entered empty.                                   | (b) (4)                 |                      |
|                                                       | Sherry McCammon (b) (4) | 19 Nov 2020 19:51:51 |
|                                                       | (b) (4)                 |                      |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:15:04

[O2 Saturation Units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '%'    | System | 19 Nov 2020 20:13:33 |
| User entered empty. | System | 19 Nov 2020 19:51:51 |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:15:04

[Temperature](#)

| Audit                                                     | User                    | Time (GMT)           |
|-----------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                       | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered '98.4' F reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 20:15:12 |
| User entered empty.                                       | Sherry McCammon (b) (4) | 19 Nov 2020 19:51:51 |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:15:04

[Chills](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'None (None)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 20:01:58 |
| User entered empty.                                            | (b) (4)                 |                      |
|                                                                | Sherry McCammon (b) (4) | 19 Nov 2020 19:51:51 |
|                                                                | (b) (4)                 |                      |



US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:15:04

[Cough](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'None (None)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 20:01:58 |
| User entered empty.                                            | (b) (4)                 |                      |
|                                                                | Sherry McCammon (b) (4) | 19 Nov 2020 19:51:51 |
|                                                                | (b) (4)                 |                      |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:15:04

[Shortness of Breath](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'None (None)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 20:03:06 |
| User entered empty.                                            | Sherry McCammon (b) (4) | 19 Nov 2020 19:51:51 |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:15:04

[Difficulty Breathing](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'None (None)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 20:04:09 |
| User entered empty.                                            | (b) (4)                 |                      |
|                                                                | Sherry McCammon (b) (4) | 19 Nov 2020 19:51:51 |
|                                                                | (b) (4)                 |                      |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:15:04

[Fatigue](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'None (None)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 20:04:09 |
| User entered empty.                                            | (b) (4)                 |                      |
|                                                                | Sherry McCammon (b) (4) | 19 Nov 2020 19:51:51 |
|                                                                | (b) (4)                 |                      |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:15:04

[Muscle Aches \(Myalgia\)](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'Mild (Mild)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 19:55:43 |
| User entered empty.                                            | Sherry McCammon (b) (4) | 19 Nov 2020 19:51:51 |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:15:04

[Body Aches](#)

| Audit                                                                  | User                    | Time (GMT)           |
|------------------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                                    | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'Moderate (Moderate)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 19:59:18 |
| User entered empty.                                                    | (b) (4)                 |                      |
|                                                                        | Sherry McCammon (b) (4) | 19 Nov 2020 19:51:51 |
|                                                                        | (b) (4)                 |                      |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:15:04

[Headache](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'Mild (Mild)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 19:57:50 |
| User entered empty.                                            | (b) (4)                 |                      |
|                                                                | Sherry McCammon (b) (4) | 19 Nov 2020 19:51:51 |
|                                                                | (b) (4)                 |                      |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:15:04

[New Loss of Taste](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'None (None)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 20:06:29 |
| User entered empty.                                            | Sherry McCammon (b) (4) | 19 Nov 2020 19:51:51 |



US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:15:04

[New Loss of Smell](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'None (None)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 20:06:29 |
| User entered empty.                                            | Sherry McCammon (b) (4) | 19 Nov 2020 19:51:51 |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:15:04

[Nasal Congestion](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'None (None)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 20:08:11 |
| User entered empty.                                            | (b) (4)                 |                      |
|                                                                | Sherry McCammon (b) (4) | 19 Nov 2020 19:51:51 |
|                                                                | (b) (4)                 |                      |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:15:04

[Runny Nose \(Rhinorrhea\)](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'None (None)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 20:08:11 |
| User entered empty.                                            | (b) (4)                 |                      |
|                                                                | Sherry McCammon (b) (4) | 19 Nov 2020 19:51:51 |
|                                                                | (b) (4)                 |                      |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:15:04

[Nausea](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'None (None)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 20:09:01 |
| User entered empty.                                            | (b) (4)                 |                      |
|                                                                | Sherry McCammon (b) (4) | 19 Nov 2020 19:51:51 |
|                                                                | (b) (4)                 |                      |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:15:04

[Vomiting](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'None (None)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 20:10:25 |
| User entered empty.                                            | Sherry McCammon (b) (4) | 19 Nov 2020 19:51:51 |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:15:04

[Diarrhea](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'None (None)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 20:11:26 |
| User entered empty.                                            | Sherry McCammon (b) (4) | 19 Nov 2020 19:51:51 |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:15:04

[Sore Throat](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'None (None)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 20:12:16 |
| User entered empty.                                            | Sherry McCammon (b) (4) | 19 Nov 2020 19:51:51 |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 11:15:04

[Symptom Day](#)

| Audit                                             | User            | Time (GMT)                   |
|---------------------------------------------------|-----------------|------------------------------|
| User entered 'Day 13 (Day 13)' reason for change: | Sherry McCammon | (b) (4) 19 Nov 2020 19:52:17 |
| Data Entry Error                                  | (b) (4)         |                              |
| User entered empty.                               | Sherry McCammon | (b) (4) 19 Nov 2020 19:52:01 |
|                                                   | (b) (4)         |                              |



US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 11:15:04

[Date](#)

| Audit                      | User                    | Time (GMT)           |
|----------------------------|-------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered '11 Nov 2020' | Sherry McCammon (b) (4) | 19 Nov 2020 19:52:01 |
|                            | (b) (4)                 |                      |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 11:15:04

[Assessment Not Done](#)

| Audit               | User                    | Time (GMT)           |
|---------------------|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered '0'    | Sherry McCammon (b) (4) | 19 Nov 2020 19:52:01 |
|                     | (b) (4)                 |                      |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 11:15:04

[O2 Saturation](#)

| Audit                                                 | User                    | Time (GMT)           |
|-------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                   | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered '98' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 20:13:33 |
| User entered empty.                                   | (b) (4)                 |                      |
|                                                       | Sherry McCammon (b) (4) | 19 Nov 2020 19:52:01 |
|                                                       | (b) (4)                 |                      |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 11:15:04

[O2 Saturation Units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '%'    | System | 19 Nov 2020 20:13:33 |
| User entered empty. | System | 19 Nov 2020 19:52:01 |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 11:15:04

[Temperature](#)

| Audit                                                     | User                    | Time (GMT)           |
|-----------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                       | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered '98.3' F reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 20:15:12 |
| User entered empty.                                       | Sherry McCammon (b) (4) | 19 Nov 2020 19:52:01 |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 11:15:04

[Chills](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'None (None)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 20:01:58 |
| User entered empty.                                            | (b) (4)                 |                      |
|                                                                | Sherry McCammon (b) (4) | 19 Nov 2020 19:52:01 |
|                                                                | (b) (4)                 |                      |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 11:15:04

[Cough](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'None (None)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 20:01:58 |
| User entered empty.                                            | (b) (4)                 |                      |
|                                                                | Sherry McCammon (b) (4) | 19 Nov 2020 19:52:01 |
|                                                                | (b) (4)                 |                      |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 11:15:04

[Shortness of Breath](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'None (None)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 20:03:06 |
| User entered empty.                                            | (b) (4)                 |                      |
|                                                                | Sherry McCammon (b) (4) | 19 Nov 2020 19:52:01 |
|                                                                | (b) (4)                 |                      |



US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 11:15:04

[Difficulty Breathing](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'None (None)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 20:04:09 |
| User entered empty.                                            | Sherry McCammon (b) (4) | 19 Nov 2020 19:52:01 |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 11:15:04

[Fatigue](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'None (None)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 20:04:09 |
| User entered empty.                                            | (b) (4)                 |                      |
|                                                                | Sherry McCammon (b) (4) | 19 Nov 2020 19:52:01 |
|                                                                | (b) (4)                 |                      |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 11:15:04

[Muscle Aches \(Myalgia\)](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'Mild (Mild)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 19:55:43 |
| User entered empty.                                            | (b) (4)                 |                      |
|                                                                | Sherry McCammon (b) (4) | 19 Nov 2020 19:52:01 |
|                                                                | (b) (4)                 |                      |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 11:15:04

[Body Aches](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'Mild (Mild)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 19:59:18 |
| User entered empty.                                            | (b) (4)                 |                      |
|                                                                | Sherry McCammon (b) (4) | 19 Nov 2020 19:52:01 |
|                                                                | (b) (4)                 |                      |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 11:15:04

[Headache](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'None (None)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 19:57:50 |
| User entered empty.                                            | (b) (4)                 |                      |
|                                                                | Sherry McCammon (b) (4) | 19 Nov 2020 19:52:01 |
|                                                                | (b) (4)                 |                      |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 11:15:04

[New Loss of Taste](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'None (None)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 20:06:29 |
| User entered empty.                                            | Sherry McCammon (b) (4) | 19 Nov 2020 19:52:01 |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 11:15:04

[New Loss of Smell](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'None (None)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 20:06:29 |
| User entered empty.                                            | Sherry McCammon (b) (4) | 19 Nov 2020 19:52:01 |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 11:15:04

[Nasal Congestion](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'None (None)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 20:08:11 |
| User entered empty.                                            | (b) (4)                 |                      |
|                                                                | Sherry McCammon (b) (4) | 19 Nov 2020 19:52:01 |
|                                                                | (b) (4)                 |                      |



US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 11:15:04

[Runny Nose \(Rhinorrhea\)](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'None (None)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 20:08:11 |
| User entered empty.                                            | (b) (4)                 |                      |
|                                                                | Sherry McCammon (b) (4) | 19 Nov 2020 19:52:01 |
|                                                                | (b) (4)                 |                      |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 11:15:04

[Nausea](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'None (None)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 20:09:01 |
| User entered empty.                                            | (b) (4)                 |                      |
|                                                                | Sherry McCammon (b) (4) | 19 Nov 2020 19:52:01 |
|                                                                | (b) (4)                 |                      |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 11:15:04

[Vomiting](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'None (None)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 20:10:25 |
| User entered empty.                                            | (b) (4)                 |                      |
|                                                                | Sherry McCammon (b) (4) | 19 Nov 2020 19:52:01 |
|                                                                | (b) (4)                 |                      |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 11:15:04

[Diarrhea](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'None (None)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 20:11:26 |
| User entered empty.                                            | Sherry McCammon (b) (4) | 19 Nov 2020 19:52:01 |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 11:15:04

[Sore Throat](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'None (None)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 20:12:16 |
| User entered empty.                                            | Sherry McCammon (b) (4) | 19 Nov 2020 19:52:01 |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 11:15:04

[Symptom Day](#)

| Audit                          | User                    | Time (GMT)           |
|--------------------------------|-------------------------|----------------------|
| User entered 'Day 14 (Day 14)' | Sherry McCammon (b) (4) | 19 Nov 2020 19:52:17 |
|                                | (b) (4)                 |                      |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 11:15:04

[Date](#)

| Audit                      | User                    | Time (GMT)           |
|----------------------------|-------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered '12 Nov 2020' | Sherry McCammon (b) (4) | 19 Nov 2020 19:52:17 |
|                            | (b) (4)                 |                      |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 11:15:04

[Assessment Not Done](#)

| Audit               | User                    | Time (GMT)           |
|---------------------|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered '0'    | Sherry McCammon (b) (4) | 19 Nov 2020 19:52:17 |
|                     | (b) (4)                 |                      |



US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 11:15:04

[O2 Saturation](#)

| Audit                                                 | User                    | Time (GMT)           |
|-------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                   | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered '98' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 20:13:33 |
| User entered empty.                                   | Sherry McCammon (b) (4) | 19 Nov 2020 19:52:17 |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 11:15:04

[O2 Saturation Units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '%'    | System | 19 Nov 2020 20:13:33 |
| User entered empty. | System | 19 Nov 2020 19:52:17 |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 11:15:04

[Temperature](#)

| Audit                                                     | User                    | Time (GMT)           |
|-----------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                       | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered '98.5' F reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 20:15:12 |
| User entered empty.                                       | Sherry McCammon (b) (4) | 19 Nov 2020 19:52:17 |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 11:15:04

[Chills](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'None (None)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 20:01:58 |
| User entered empty.                                            | (b) (4)                 |                      |
|                                                                | Sherry McCammon (b) (4) | 19 Nov 2020 19:52:17 |
|                                                                | (b) (4)                 |                      |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 11:15:04

[Cough](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'None (None)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 20:01:58 |
| User entered empty.                                            | (b) (4)                 |                      |
|                                                                | Sherry McCammon (b) (4) | 19 Nov 2020 19:52:17 |
|                                                                | (b) (4)                 |                      |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 11:15:04

[Shortness of Breath](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'None (None)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 20:03:06 |
| User entered empty.                                            | Sherry McCammon (b) (4) | 19 Nov 2020 19:52:17 |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 11:15:04

[Difficulty Breathing](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'None (None)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 20:04:09 |
| User entered empty.                                            | (b) (4)                 |                      |
|                                                                | Sherry McCammon (b) (4) | 19 Nov 2020 19:52:17 |
|                                                                | (b) (4)                 |                      |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 11:15:04

[Fatigue](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'None (None)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 20:04:09 |
| User entered empty.                                            | (b) (4)                 |                      |
|                                                                | Sherry McCammon (b) (4) | 19 Nov 2020 19:52:17 |
|                                                                | (b) (4)                 |                      |



US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 11:15:04

[Muscle Aches \(Myalgia\)](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'Mild (Mild)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 19:55:43 |
| User entered empty.                                            | (b) (4)                 |                      |
|                                                                | Sherry McCammon (b) (4) | 19 Nov 2020 19:52:17 |
|                                                                | (b) (4)                 |                      |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 11:15:04

[Body Aches](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'Mild (Mild)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 19:59:18 |
| User entered empty.                                            | Sherry McCammon (b) (4) | 19 Nov 2020 19:52:17 |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 11:15:04

[Headache](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'None (None)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 19:57:50 |
| User entered empty.                                            | (b) (4)                 |                      |
|                                                                | Sherry McCammon (b) (4) | 19 Nov 2020 19:52:17 |
|                                                                | (b) (4)                 |                      |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 11:15:04

[New Loss of Taste](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'None (None)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 20:06:29 |
| User entered empty.                                            | Sherry McCammon (b) (4) | 19 Nov 2020 19:52:17 |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 11:15:04

[New Loss of Smell](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'None (None)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 20:06:29 |
| User entered empty.                                            | Sherry McCammon (b) (4) | 19 Nov 2020 19:52:17 |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 11:15:04

[Nasal Congestion](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'None (None)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 20:08:11 |
| User entered empty.                                            | (b) (4)                 |                      |
|                                                                | Sherry McCammon (b) (4) | 19 Nov 2020 19:52:17 |
|                                                                | (b) (4)                 |                      |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 11:15:04

[Runny Nose \(Rhinorrhea\)](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'None (None)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 20:08:11 |
| User entered empty.                                            | (b) (4)                 |                      |
|                                                                | Sherry McCammon (b) (4) | 19 Nov 2020 19:52:17 |
|                                                                | (b) (4)                 |                      |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 11:15:04

[Nausea](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'None (None)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 20:09:01 |
| User entered empty.                                            | (b) (4)                 |                      |
|                                                                | Sherry McCammon (b) (4) | 19 Nov 2020 19:52:17 |
|                                                                | (b) (4)                 |                      |



US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 11:15:04

[Vomiting](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'None (None)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 20:10:25 |
| User entered empty.                                            | Sherry McCammon (b) (4) | 19 Nov 2020 19:52:17 |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 11:15:04

[Diarrhea](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'None (None)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 20:11:26 |
| User entered empty.                                            | Sherry McCammon (b) (4) | 19 Nov 2020 19:52:17 |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 11:15:04

[Sore Throat](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'None (None)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 20:12:16 |
| User entered empty.                                            | Sherry McCammon (b) (4) | 19 Nov 2020 19:52:17 |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 11:15:04

[Symptom Day](#)

| Audit                          | User                    | Time (GMT)           |
|--------------------------------|-------------------------|----------------------|
| User entered 'Day 15 (Day 15)' | Sherry McCammon (b) (4) | 19 Nov 2020 19:52:37 |
|                                | (b) (4)                 |                      |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 11:15:04

[Date](#)

| Audit                      | User                    | Time (GMT)           |
|----------------------------|-------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered '13 Nov 2020' | Sherry McCammon (b) (4) | 19 Nov 2020 19:52:37 |
|                            | (b) (4)                 |                      |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 11:15:04

[Assessment Not Done](#)

| Audit               | User                    | Time (GMT)           |
|---------------------|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered '0'    | Sherry McCammon (b) (4) | 19 Nov 2020 19:52:37 |
|                     | (b) (4)                 |                      |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 11:15:04

[O2 Saturation](#)

| Audit                                                 | User                    | Time (GMT)           |
|-------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                   | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered '98' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 20:13:33 |
| User entered empty.                                   | (b) (4)                 |                      |
|                                                       | Sherry McCammon (b) (4) | 19 Nov 2020 19:52:37 |
|                                                       | (b) (4)                 |                      |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 11:15:04

[O2 Saturation Units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '%'    | System | 19 Nov 2020 20:13:33 |
| User entered empty. | System | 19 Nov 2020 19:52:37 |



US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 11:15:04

[Temperature](#)

| Audit                                                     | User                    | Time (GMT)           |
|-----------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                       | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered '98.3' F reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 20:15:12 |
| User entered empty.                                       | Sherry McCammon (b) (4) | 19 Nov 2020 19:52:37 |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 11:15:04

[Chills](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'None (None)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 20:01:58 |
| User entered empty.                                            | (b) (4)                 |                      |
|                                                                | Sherry McCammon (b) (4) | 19 Nov 2020 19:52:37 |
|                                                                | (b) (4)                 |                      |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 11:15:04

[Cough](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'None (None)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 20:01:58 |
| User entered empty.                                            | (b) (4)                 |                      |
|                                                                | Sherry McCammon (b) (4) | 19 Nov 2020 19:52:37 |
|                                                                | (b) (4)                 |                      |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 11:15:04

[Shortness of Breath](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'None (None)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 20:03:06 |
| User entered empty.                                            | Sherry McCammon (b) (4) | 19 Nov 2020 19:52:37 |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 11:15:04

[Difficulty Breathing](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'None (None)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 20:04:09 |
| User entered empty.                                            | (b) (4)                 |                      |
|                                                                | Sherry McCammon (b) (4) | 19 Nov 2020 19:52:37 |
|                                                                | (b) (4)                 |                      |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 11:15:04

[Fatigue](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'None (None)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 20:04:09 |
| User entered empty.                                            | (b) (4)                 |                      |
|                                                                | Sherry McCammon (b) (4) | 19 Nov 2020 19:52:37 |
|                                                                | (b) (4)                 |                      |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 11:15:04

[Muscle Aches \(Myalgia\)](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'Mild (Mild)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 19:55:43 |
| User entered empty.                                            | Sherry McCammon (b) (4) | 19 Nov 2020 19:52:37 |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 11:15:04

[Body Aches](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'Mild (Mild)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 19:59:18 |
| User entered empty.                                            | Sherry McCammon (b) (4) | 19 Nov 2020 19:52:37 |



US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 11:15:04

[Headache](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'None (None)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 19:57:50 |
| User entered empty.                                            | (b) (4)                 |                      |
|                                                                | Sherry McCammon (b) (4) | 19 Nov 2020 19:52:37 |
|                                                                | (b) (4)                 |                      |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 11:15:04

[New Loss of Taste](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'None (None)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 20:06:29 |
| User entered empty.                                            | Sherry McCammon (b) (4) | 19 Nov 2020 19:52:37 |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 11:15:04

[New Loss of Smell](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'None (None)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 20:06:29 |
| User entered empty.                                            | Sherry McCammon (b) (4) | 19 Nov 2020 19:52:37 |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 11:15:04

[Nasal Congestion](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'None (None)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 20:08:11 |
| User entered empty.                                            | (b) (4)                 |                      |
|                                                                | Sherry McCammon (b) (4) | 19 Nov 2020 19:52:37 |
|                                                                | (b) (4)                 |                      |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 11:15:04

[Runny Nose \(Rhinorrhea\)](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'None (None)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 20:08:11 |
| User entered empty.                                            | (b) (4)                 |                      |
|                                                                | Sherry McCammon (b) (4) | 19 Nov 2020 19:52:37 |
|                                                                | (b) (4)                 |                      |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 11:15:04

[Nausea](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'None (None)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 20:09:01 |
| User entered empty.                                            | (b) (4)                 |                      |
|                                                                | Sherry McCammon (b) (4) | 19 Nov 2020 19:52:37 |
|                                                                | (b) (4)                 |                      |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 11:15:04

[Vomiting](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'None (None)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 20:10:25 |
| User entered empty.                                            | Sherry McCammon (b) (4) | 19 Nov 2020 19:52:37 |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 11:15:04

[Diarrhea](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'None (None)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 20:11:26 |
| User entered empty.                                            | Sherry McCammon (b) (4) | 19 Nov 2020 19:52:37 |



US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 11:15:04

[Sore Throat](#)

| Audit                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)        | 23 Nov 2020 16:39:08 |
| User entered 'None (None)' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 19 Nov 2020 20:12:16 |
| User entered empty.                                            | Sherry McCammon (b) (4) | 19 Nov 2020 19:52:37 |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 11:15:04

[Date of Visit](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 10 Nov 2020 17:42:00 |
| User entered '06 Nov 2020' | (b) (4), (b) (6) | 10 Nov 2020 17:28:25 |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 11:15:04

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 10 Nov 2020 17:42:00 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 10 Nov 2020 17:28:25 |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 11:15:04

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

| Audit                                                                                                         | User                    | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                                                                           | (b) (4), (b) (6)        | 23 Nov 2020 16:37:42 |
| User closed query 'per CDM RQ: please respond to this query when data is entered' (Site from DM).             | (b) (4), (b) (6)        | 23 Nov 2020 12:48:55 |
| Query 'per CDM RQ: please respond to this query when data is entered' answered with 'updated' (Site from DM). | Sherry McCammon (b) (4) | 20 Nov 2020 14:44:52 |
| User entered 'No (N)' reason for change: Data Entry Error                                                     | Sherry McCammon (b) (4) | 20 Nov 2020 14:44:39 |
| User closed query 'Data is required. Please complete.' (Site from System).                                    | (b) (4), (b) (6)        | 19 Nov 2020 17:03:19 |
| User opened query 'per CDM RQ: please respond to this query when data is entered' (Site from DM).             | (b) (4), (b) (6)        | 19 Nov 2020 17:03:18 |
| DataPoint Un-verified.                                                                                        | (b) (4), (b) (6)        | 10 Nov 2020 17:42:04 |
| DataPoint Verified.                                                                                           | (b) (4), (b) (6)        | 10 Nov 2020 17:42:00 |
| Query 'Data is required. Please complete.' answered with 'Pending' (Site from System).                        | (b) (4), (b) (6)        | 10 Nov 2020 17:28:59 |
| User opened query 'Data is required. Please complete.' (Site from System).                                    | System                  | 10 Nov 2020 17:28:25 |
| User entered empty.                                                                                           | (b) (4), (b) (6)        | 10 Nov 2020 17:28:25 |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 11:15:04

[Date of Test](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 10 Nov 2020 17:42:00 |
| User entered '06 Nov 2020' | (b) (4), (b) (6) | 10 Nov 2020 17:28:25 |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 11:15:04

[Type of Test Performed](#)

| Audit                                                    | User             | Time (GMT)           |
|----------------------------------------------------------|------------------|----------------------|
| DataPoint Verified.                                      | (b) (4), (b) (6) | 10 Nov 2020 17:42:00 |
| User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)' | (b) (4), (b) (6) | 10 Nov 2020 17:28:25 |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 11:15:04

[Other, specify](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 10 Nov 2020 17:42:00 |
| User entered empty. | (b) (4), (b) (6) | 10 Nov 2020 17:28:25 |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 11:15:04

[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 10 Nov 2020 17:42:00 |
| User entered 'No (N)' | (b) (4), (b) (6) | 10 Nov 2020 17:28:25 |



US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 11:15:04

[Lab/ Institution Test Performed](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 10 Nov 2020 17:42:00 |
| User entered empty. | (b) (4), (b) (6) | 10 Nov 2020 17:28:25 |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 11:15:04

[CLIA Certified?](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 10 Nov 2020 17:42:00 |
| User entered empty. | (b) (4), (b) (6) | 10 Nov 2020 17:28:25 |

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 11:15:04

[COVID-19 Positive \(CSA Programming Field Only\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '0' | System | 20 Nov 2020 14:44:39 |

US3742169

**Folder: Illness Visit (1)**

**Form: Saliva Collection (1)**

**Generated On: 26 Nov 2020 11:15:04**

[Visit](#)

| Audit                                       | User                           | Time (GMT)           |
|---------------------------------------------|--------------------------------|----------------------|
| User accepted default value 'Day 3 (Day 3)' | Hassan Haji (b) (4)<br>(b) (4) | 19 Nov 2020 15:18:13 |

US3742169

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 26 Nov 2020 11:15:04

[Was Saliva Collected?](#)

| Audit                  | User                           | Time (GMT)           |
|------------------------|--------------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)               | 23 Nov 2020 16:38:02 |
| User entered 'Yes (Y)' | Hassan Haji (b) (4)<br>(b) (4) | 19 Nov 2020 15:18:13 |

US3742169

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 26 Nov 2020 11:15:04

[Date of Collection](#)

| Audit                     | User                           | Time (GMT)           |
|---------------------------|--------------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)               | 23 Nov 2020 16:38:02 |
| User entered '8 Nov 2020' | Hassan Haji (b) (4)<br>(b) (4) | 19 Nov 2020 15:18:13 |

US3742169

**Folder: Illness Visit (1)**

**Form: Saliva Collection (2)**

**Generated On: 26 Nov 2020 11:15:04**

[Visit](#)

| Audit                                       | User                           | Time (GMT)           |
|---------------------------------------------|--------------------------------|----------------------|
| User accepted default value 'Day 5 (Day 5)' | Hassan Haji (b) (4)<br>(b) (4) | 19 Nov 2020 15:18:13 |

US3742169

**Folder: Illness Visit (1)**

**Form: Saliva Collection (2)**

**Generated On: 26 Nov 2020 11:15:04**

[Was Saliva Collected?](#)

| Audit                  | User                           | Time (GMT)           |
|------------------------|--------------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)               | 23 Nov 2020 16:38:02 |
| User entered 'Yes (Y)' | Hassan Haji (b) (4)<br>(b) (4) | 19 Nov 2020 15:18:13 |



US3742169

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 26 Nov 2020 11:15:04

[Date of Collection](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 23 Nov 2020 16:38:02 |
| User entered '10 Nov 2020' | Hassan Haji (b) (4)<br>(b) (4) | 19 Nov 2020 15:18:13 |

US3742169

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 26 Nov 2020 11:15:04

[Visit](#)

| Audit                                       | User                           | Time (GMT)           |
|---------------------------------------------|--------------------------------|----------------------|
| User accepted default value 'Day 7 (Day 7)' | Hassan Haji (b) (4)<br>(b) (4) | 19 Nov 2020 15:18:13 |

US3742169

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 26 Nov 2020 11:15:04

[Was Saliva Collected?](#)

| Audit                  | User                           | Time (GMT)           |
|------------------------|--------------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)               | 23 Nov 2020 16:38:02 |
| User entered 'Yes (Y)' | Hassan Haji (b) (4)<br>(b) (4) | 19 Nov 2020 15:18:13 |

US3742169

**Folder: Illness Visit (1)**

**Form: Saliva Collection (3)**

**Generated On: 26 Nov 2020 11:15:04**

[Date of Collection](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 23 Nov 2020 16:38:02 |
| User entered '12 Nov 2020' | Hassan Haji (b) (4)<br>(b) (4) | 19 Nov 2020 15:18:13 |

US3742169

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 26 Nov 2020 11:15:04

[Visit](#)

| Audit                                       | User                           | Time (GMT)           |
|---------------------------------------------|--------------------------------|----------------------|
| User accepted default value 'Day 9 (Day 9)' | Hassan Haji (b) (4)<br>(b) (4) | 19 Nov 2020 15:18:13 |

US3742169

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 26 Nov 2020 11:15:04

[Was Saliva Collected?](#)

| Audit                                      | User                           | Time (GMT)           |
|--------------------------------------------|--------------------------------|----------------------|
| DataPoint Verified.                        | (b) (4), (b) (6)               | 23 Nov 2020 16:38:02 |
| User entered 'NA (COVID-19 Negative) (NA)' | Hassan Haji (b) (4)<br>(b) (4) | 19 Nov 2020 15:18:13 |

US3742169

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 26 Nov 2020 11:15:04

[Date of Collection](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 23 Nov 2020 16:38:02 |
| User entered empty. | Hassan Haji (b) (4)<br>(b) (4) | 19 Nov 2020 15:18:13 |

US3742169

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 26 Nov 2020 11:15:04

[Visit](#)

| Audit                                         | User                           | Time (GMT)           |
|-----------------------------------------------|--------------------------------|----------------------|
| User accepted default value 'Day 14 (Day 14)' | Hassan Haji (b) (4)<br>(b) (4) | 19 Nov 2020 15:18:13 |



US3742169

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 26 Nov 2020 11:15:04

[Was Saliva Collected?](#)

| Audit                                      | User                           | Time (GMT)           |
|--------------------------------------------|--------------------------------|----------------------|
| DataPoint Verified.                        | (b) (4), (b) (6)               | 23 Nov 2020 16:38:02 |
| User entered 'NA (COVID-19 Negative) (NA)' | Hassan Haji (b) (4)<br>(b) (4) | 19 Nov 2020 15:18:13 |

US3742169

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 26 Nov 2020 11:15:04

[Date of Collection](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 23 Nov 2020 16:38:02 |
| User entered empty. | Hassan Haji (b) (4)<br>(b) (4) | 19 Nov 2020 15:18:13 |

US3742169

**Folder: Illness Visit (1)**

**Form: Saliva Collection (6)**

**Generated On: 26 Nov 2020 11:15:04**

[Visit](#)

| Audit                                         | User                           | Time (GMT)           |
|-----------------------------------------------|--------------------------------|----------------------|
| User accepted default value 'Day 21 (Day 21)' | Hassan Haji (b) (4)<br>(b) (4) | 19 Nov 2020 15:18:13 |

US3742169

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 26 Nov 2020 11:15:04

[Was Saliva Collected?](#)

| Audit                                      | User                           | Time (GMT)           |
|--------------------------------------------|--------------------------------|----------------------|
| DataPoint Verified.                        | (b) (4), (b) (6)               | 23 Nov 2020 16:38:02 |
| User entered 'NA (COVID-19 Negative) (NA)' | Hassan Haji (b) (4)<br>(b) (4) | 19 Nov 2020 15:18:13 |

US3742169

**Folder: Illness Visit (1)**

**Form: Saliva Collection (6)**

**Generated On: 26 Nov 2020 11:15:04**

[Date of Collection](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 23 Nov 2020 16:38:02 |
| User entered empty. | Hassan Haji (b) (4)<br>(b) (4) | 19 Nov 2020 15:18:13 |

US3742169

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 26 Nov 2020 11:15:04

[Visit](#)

| Audit                                         | User                           | Time (GMT)           |
|-----------------------------------------------|--------------------------------|----------------------|
| User accepted default value 'Day 28 (Day 28)' | Hassan Haji (b) (4)<br>(b) (4) | 19 Nov 2020 15:18:13 |

US3742169

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 26 Nov 2020 11:15:04

[Was Saliva Collected?](#)

| Audit                                      | User                           | Time (GMT)           |
|--------------------------------------------|--------------------------------|----------------------|
| DataPoint Verified.                        | (b) (4), (b) (6)               | 23 Nov 2020 16:38:02 |
| User entered 'NA (COVID-19 Negative) (NA)' | Hassan Haji (b) (4)<br>(b) (4) | 19 Nov 2020 15:18:13 |

US3742169

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 26 Nov 2020 11:15:04

[Date of Collection](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 23 Nov 2020 16:38:02 |
| User entered empty. | Hassan Haji (b) (4)<br>(b) (4) | 19 Nov 2020 15:18:13 |



US3742169

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:15:04

[Was this visit performed?](#)

| Audit                                                                                                                                                                                                                                                        | User                               | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------|----------------------|
| User closed query 'Per GCL Lab Reconciliation: it appears PPD Central lab has Swab sample with date 06NOV2020 under illness visit; however, there is no record in EDC. Please confirm the correct visit and update accordingly.' (Site from DM).             | (b) (4), (b) (6)                   | 23 Nov 2020 12:49:06 |
| Query 'Per GCL Lab Reconciliation: it appears PPD Central lab has Swab sample with date 06NOV2020 under illness visit; however, there is no record in EDC. Please confirm the correct visit and update accordingly.' answered with 'updated' (Site from DM). | Kaitlin Mason (b) (4)<br>(b) (4)   | 13 Nov 2020 18:51:30 |
| User opened query 'Per GCL Lab Reconciliation: it appears PPD Central lab has Swab sample with date 06NOV2020 under illness visit; however, there is no record in EDC. Please confirm the correct visit and update accordingly.' (Site from DM).             | (b) (4), (b) (6)                   | 13 Nov 2020 05:37:30 |
| DataPoint Verified.                                                                                                                                                                                                                                          | (b) (4), (b) (6)                   | 10 Nov 2020 16:45:44 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                                       | Sherry McCammon (b) (4)<br>(b) (4) | 06 Nov 2020 18:51:34 |

US3742169

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 26 Nov 2020 11:15:04**

[Visit date \(dd MMM yyyy\)](#)

| Audit                      | User                    | Time (GMT)           |
|----------------------------|-------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)        | 10 Nov 2020 16:45:44 |
| User entered '06 Nov 2020' | Sherry McCammon (b) (4) | 06 Nov 2020 18:51:34 |
|                            | (b) (4)                 |                      |

US3742169

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:15:04

[Was visit performed at the participant's home or at the clinic?](#)

| Audit                          | User                    | Time (GMT)           |
|--------------------------------|-------------------------|----------------------|
| DataPoint Verified.            | (b) (4), (b) (6)        | 10 Nov 2020 16:45:44 |
| User entered 'Clinic (Clinic)' | Sherry McCammon (b) (4) | 06 Nov 2020 18:51:34 |
|                                | (b) (4)                 |                      |

**US3742169**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 26 Nov 2020 11:15:04**

[Folder OID](#)

| Audit                 | User   | Time (GMT)           |
|-----------------------|--------|----------------------|
| User entered 'SICKD1' | System | 06 Nov 2020 18:51:34 |

US3742169

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:04

[Were vital signs assessed?](#)

| Audit                  | User                    | Time (GMT)           |
|------------------------|-------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)        | 10 Nov 2020 16:48:51 |
| User entered 'Yes (Y)' | Sherry McCammon (b) (4) | 06 Nov 2020 18:53:20 |
|                        | (b) (4)                 |                      |

US3742169

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:04

Date of assessment (*dd MMM yyyy*)

| Audit                      | User                    | Time (GMT)           |
|----------------------------|-------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)        | 10 Nov 2020 16:48:51 |
| User entered '06 Nov 2020' | Sherry McCammon (b) (4) | 06 Nov 2020 18:53:20 |
|                            | (b) (4)                 |                      |

US3742169

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 11:15:04**

[Time of assessment \(00:00-23:59\)](#)

| Audit                | User                    | Time (GMT)           |
|----------------------|-------------------------|----------------------|
| DataPoint Verified.  | (b) (4), (b) (6)        | 10 Nov 2020 16:48:51 |
| User entered '12:20' | Sherry McCammon (b) (4) | 06 Nov 2020 18:53:20 |
|                      | (b) (4)                 |                      |

US3742169

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 11:15:04**

[Vital Signs Date and Time \(derived\)](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '06 Nov 2020 12:20' | System | 06 Nov 2020 18:53:20 |



US3742169

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:04

[Height \(xxx.x\)](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)        | 10 Nov 2020 16:48:51 |
| User entered '67.0' in    | Sherry McCammon (b) (4) | 06 Nov 2020 18:53:20 |
| DataPoint set to visible. | (b) (4)<br>System       | 06 Nov 2020 18:51:34 |

US3742169

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:04

Weight (xxx.x)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)        | 10 Nov 2020 16:48:51 |
| User entered '197.0' lb   | Sherry McCammon (b) (4) | 06 Nov 2020 18:53:20 |
| DataPoint set to visible. | (b) (4)<br>System       | 06 Nov 2020 18:51:34 |

US3742169

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:04

Temperature (xxx.x)

| Audit                  | User                    | Time (GMT)           |
|------------------------|-------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)        | 10 Nov 2020 16:48:51 |
| User entered '098.0' F | Sherry McCammon (b) (4) | 06 Nov 2020 18:53:20 |
|                        | (b) (4)                 |                      |

US3742169

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:04

[Route of measurement](#)

| Audit                      | User                    | Time (GMT)           |
|----------------------------|-------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)        | 10 Nov 2020 16:48:51 |
| User entered 'Oral (Oral)' | Sherry McCammon (b) (4) | 06 Nov 2020 18:53:20 |
|                            | (b) (4)                 |                      |

US3742169

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:04

[If Other, specify](#)

| Audit               | User                    | Time (GMT)           |
|---------------------|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)        | 10 Nov 2020 16:48:51 |
| User entered empty. | Sherry McCammon (b) (4) | 06 Nov 2020 18:53:20 |
|                     | (b) (4)                 |                      |

US3742169

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:04

[Pulse \(xxx\)](#)

| Audit                                                  | User                    | Time (GMT)           |
|--------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                    | (b) (4), (b) (6)        | 10 Nov 2020 16:48:51 |
| User entered '063' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 06 Nov 2020 18:54:01 |
| User entered '097'                                     | Sherry McCammon (b) (4) | 06 Nov 2020 18:53:20 |

**US3742169**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 11:15:04**

[Pulse units](#)

| Audit              | User   | Time (GMT)           |
|--------------------|--------|----------------------|
| User entered 'bpm' | System | 06 Nov 2020 18:53:20 |

US3742169

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:04

[Respiratory Rate \(xxx\)](#)

| Audit                                                                                                                                                                                                  | User                    | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                                                                                                                                                                    | (b) (4), (b) (6)        | 10 Nov 2020 16:48:51 |
| User closed query 'Respiratory rate reported is out of range < 8 or > 32 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).             | System                  | 06 Nov 2020 18:54:01 |
| Query 'Respiratory rate reported is out of range < 8 or > 32 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered by data change (Site from System). | System                  | 06 Nov 2020 18:54:01 |
| User entered '14' reason for change: Data Entry Error                                                                                                                                                  | Sherry McCammon (b) (4) | 06 Nov 2020 18:54:01 |
| User opened query 'Respiratory rate reported is out of range < 8 or > 32 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).             | (b) (4)                 | 06 Nov 2020 18:53:20 |
| User entered '063'                                                                                                                                                                                     | Sherry McCammon (b) (4) | 06 Nov 2020 18:53:20 |



US3742169

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:04

[Respiratory Rate units](#)

| Audit                      | User   | Time (GMT)           |
|----------------------------|--------|----------------------|
| User entered 'breaths/min' | System | 06 Nov 2020 18:53:20 |

US3742169

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:04

Systolic Blood Pressure (xxx)

| Audit               | User                    | Time (GMT)           |
|---------------------|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)        | 10 Nov 2020 16:48:51 |
| User entered '124'  | Sherry McCammon (b) (4) | 06 Nov 2020 18:53:20 |
|                     | (b) (4)                 |                      |

US3742169

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 11:15:04**

[Systolic Blood Pressure units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 06 Nov 2020 18:53:20 |

US3742169

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 11:15:04**

[Diastolic Blood Pressure \(xxx\)](#)

| Audit               | User                    | Time (GMT)           |
|---------------------|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)        | 10 Nov 2020 16:48:51 |
| User entered '084'  | Sherry McCammon (b) (4) | 06 Nov 2020 18:53:20 |
|                     | (b) (4)                 |                      |

US3742169

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 11:15:04**

[Diastolic Blood Pressure units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 06 Nov 2020 18:53:20 |

US3742169

**Folder: Illness Visit Day 1 (1)**

**Form: Physical Examination**

**Generated On: 26 Nov 2020 11:15:04**

[Was the physical examination performed?](#)

| Audit                  | User                    | Time (GMT)           |
|------------------------|-------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)        | 10 Nov 2020 16:44:46 |
| User entered 'Yes (Y)' | Sherry McCammon (b) (4) | 06 Nov 2020 18:54:57 |
|                        | (b) (4)                 |                      |

US3742169

**Folder: Illness Visit Day 1 (1)**

**Form: Physical Examination**

**Generated On: 26 Nov 2020 11:15:04**

**Date of examination (dd MMM yyyy)**

| Audit                      | User                    | Time (GMT)           |
|----------------------------|-------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)        | 10 Nov 2020 16:44:46 |
| User entered '06 Nov 2020' | Sherry McCammon (b) (4) | 06 Nov 2020 18:54:57 |
|                            | (b) (4)                 |                      |

US3742169

**Folder: Illness Visit Day 1 (1)**

**Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection**

**Generated On: 26 Nov 2020 11:15:04**

[Was Blood Sample Taken for Immunologic Assessment of SARS\\_COV-2 Infection?](#)

| Audit                  | User                    | Time (GMT)           |
|------------------------|-------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)        | 10 Nov 2020 16:40:17 |
| User entered 'Yes (Y)' | Sherry McCammon (b) (4) | 06 Nov 2020 18:55:19 |
|                        | (b) (4)                 |                      |



US3742169

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 26 Nov 2020 11:15:04

[Date of Collection](#)

| Audit                                                                                                                                                                                                                                                                                 | User                               | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------|----------------------|
| User closed query 'Per GCL Lab Recon: Saliva: Sample dated 08Nov2020 for Day 3 , 10Nov2020 for Day 5 and 12Nov2020 for Day 7 is reported under Illness visit in PPD central lab, however saliva log is not completed in EDC. Please complete, thank you.' (Site from DM).             | (b) (4), (b) (6)                   | 24 Nov 2020 08:12:05 |
| Query 'Per GCL Lab Recon: Saliva: Sample dated 08Nov2020 for Day 3 , 10Nov2020 for Day 5 and 12Nov2020 for Day 7 is reported under Illness visit in PPD central lab, however saliva log is not completed in EDC. Please complete, thank you.' answered with 'updated' (Site from DM). | Kaitlin Mason (b) (4)<br>(b) (4)   | 19 Nov 2020 15:57:56 |
| User opened query 'Per GCL Lab Recon: Saliva: Sample dated 08Nov2020 for Day 3 , 10Nov2020 for Day 5 and 12Nov2020 for Day 7 is reported under Illness visit in PPD central lab, however saliva log is not completed in EDC. Please complete, thank you.' (Site from DM).             | (b) (4), (b) (6)                   | 18 Nov 2020 08:32:20 |
| DataPoint Verified.                                                                                                                                                                                                                                                                   | (b) (4), (b) (6)                   | 10 Nov 2020 16:40:17 |
| User entered '06 Nov 2020'                                                                                                                                                                                                                                                            | Sherry McCammon (b) (4)<br>(b) (4) | 06 Nov 2020 18:55:19 |

US3742169

**Folder:** Adverse Events

**Form:** Adverse Events Summary

**Generated On:** 26 Nov 2020 11:15:04

[Did the participant experience any adverse events?](#)

| Audit                  | User                           | Time (GMT)           |
|------------------------|--------------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)               | 01 Oct 2020 20:27:31 |
| User entered 'Yes (Y)' | Hassan Haji (b) (4)<br>(b) (4) | 17 Sep 2020 20:02:46 |

US3742169

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:04

[Adverse event](#)

| Audit                                                                                                                                                                                                                                          | User                  | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|----------------------|
| User closed query 'Per DM CLR: Other Action Taken = None. However, there is a recorded ConMed that match this AE. Please review and update Other Action Taken as appropriate. Otherwise, clarify.' (Site from DM).                             | (b) (4), (b) (6)      | 27 Oct 2020 08:51:59 |
| Query 'Per DM CLR: Other Action Taken = None. However, there is a recorded ConMed that match this AE. Please review and update Other Action Taken as appropriate. Otherwise, clarify.' answered with 'added' (Site from DM).                   | Kaitlin Mason (b) (4) | 21 Oct 2020 15:06:58 |
| User opened query 'Per DM CLR: Other Action Taken = None. However, there is a recorded ConMed that match this AE. Please review and update Other Action Taken as appropriate. Otherwise, clarify.' (Site from DM).                             | (b) (4), (b) (6)      | 20 Oct 2020 19:59:26 |
| DataPoint Verified.                                                                                                                                                                                                                            | (b) (4), (b) (6)      | 01 Oct 2020 20:32:20 |
| User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Constipation, LLT: Constipation - version MedDRA\\23.0. | Coder Import (b) (4)  | 17 Sep 2020 20:06:44 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.                                                                                                                                                   | Coder Import (b) (4)  | 17 Sep 2020 20:06:44 |
| Data point term sent to Coder                                                                                                                                                                                                                  | System                | 17 Sep 2020 20:05:28 |
| User entered 'constipation'                                                                                                                                                                                                                    | Hassan Haji (b) (4)   | 17 Sep 2020 20:05:07 |

US3742169

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:04

[Was this a medically-attended AE?](#)

| Audit                 | User                           | Time (GMT)           |
|-----------------------|--------------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)               | 01 Oct 2020 20:32:20 |
| User entered 'No (N)' | Hassan Haji (b) (4)<br>(b) (4) | 17 Sep 2020 20:05:07 |

US3742169

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:04

[Was this a Solicited Adverse Reaction?](#)

| Audit                 | User                           | Time (GMT)           |
|-----------------------|--------------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)               | 01 Oct 2020 20:32:20 |
| User entered 'No (N)' | Hassan Haji (b) (4)<br>(b) (4) | 17 Sep 2020 20:05:07 |

US3742169

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:04

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit                 | User                           | Time (GMT)           |
|-----------------------|--------------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)               | 01 Oct 2020 20:32:20 |
| User entered 'No (N)' | Hassan Haji (b) (4)<br>(b) (4) | 17 Sep 2020 20:05:07 |

US3742169

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:04

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 01 Oct 2020 20:32:20 |
| User entered '13 Sep 2020' | Hassan Haji (b) (4)<br>(b) (4) | 17 Sep 2020 20:05:07 |

US3742169

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:04

Start time (00:00-23:59)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 01 Oct 2020 20:32:20 |
| User entered empty. | Hassan Haji (b) (4)<br>(b) (4) | 17 Sep 2020 20:05:07 |



US3742169

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:04

[AE start date and time \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 17 Sep 2020 20:05:07 |

US3742169

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:04

[Ongoing?](#)

| Audit                 | User                           | Time (GMT)           |
|-----------------------|--------------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)               | 01 Oct 2020 20:32:20 |
| User entered 'No (N)' | Hassan Haji (b) (4)<br>(b) (4) | 17 Sep 2020 20:05:07 |

US3742169

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:04

If not Ongoing, end date (dd MMM yyyy)

| Audit                                                         | User                           | Time (GMT)           |
|---------------------------------------------------------------|--------------------------------|----------------------|
| DataPoint Verified.                                           | (b) (4), (b) (6)               | 14 Oct 2020 20:06:01 |
| DataPoint Un-verified.                                        | (b) (4), (b) (6)               | 06 Oct 2020 14:00:46 |
| User entered '25 Sep 2020' reason for change: New Information | (b) (4), (b) (6)               | 06 Oct 2020 14:00:46 |
| DataPoint Verified.                                           | (b) (4), (b) (6)               | 01 Oct 2020 20:32:20 |
| User entered '16 Sep 2020'                                    | Hassan Haji (b) (4)<br>(b) (4) | 17 Sep 2020 20:05:07 |

US3742169

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:04

End time (00:00-23:59)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 01 Oct 2020 20:32:20 |
| User entered empty. | Hassan Haji (b) (4)<br>(b) (4) | 17 Sep 2020 20:05:07 |

**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 11:15:04**

[AE End Date and Time \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 17 Sep 2020 20:05:07 |

US3742169

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:04

[Severity](#)

| Audit                                              | User                           | Time (GMT)           |
|----------------------------------------------------|--------------------------------|----------------------|
| DataPoint Verified.                                | (b) (4), (b) (6)               | 01 Oct 2020 20:32:20 |
| User entered 'Grade 2/Moderate (Grade 2/Moderate)' | Hassan Haji (b) (4)<br>(b) (4) | 17 Sep 2020 20:05:07 |

US3742169

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:04

[Is the adverse event serious?](#)

| Audit                 | User                           | Time (GMT)           |
|-----------------------|--------------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)               | 01 Oct 2020 20:32:20 |
| User entered 'No (N)' | Hassan Haji (b) (4)<br>(b) (4) | 17 Sep 2020 20:05:07 |

US3742169

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:04

[Death](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 01 Oct 2020 20:32:20 |
| User entered '0'    | Hassan Haji (b) (4)<br>(b) (4) | 17 Sep 2020 20:05:07 |



US3742169

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:04

[Life threatening](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 01 Oct 2020 20:32:20 |
| User entered '0'    | Hassan Haji (b) (4)<br>(b) (4) | 17 Sep 2020 20:05:07 |

US3742169

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:04

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 01 Oct 2020 20:32:20 |
| User entered '0'    | Hassan Haji (b) (4)<br>(b) (4) | 17 Sep 2020 20:05:07 |

US3742169

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:04

Hospital Admission Date (*dd MMM yyyy*)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 01 Oct 2020 20:32:20 |
| User entered empty. | Hassan Haji (b) (4)<br>(b) (4) | 17 Sep 2020 20:05:07 |

US3742169

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:04

Hospital Discharge Date (dd MMM yyyy)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 01 Oct 2020 20:32:20 |
| User entered empty. | Hassan Haji (b) (4)<br>(b) (4) | 17 Sep 2020 20:05:07 |

US3742169

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:04

[Admitted to ICU?](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 01 Oct 2020 20:32:20 |
| User entered empty. | Hassan Haji (b) (4)<br>(b) (4) | 17 Sep 2020 20:05:07 |

US3742169

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:04

[Number of Days in ICU](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 01 Oct 2020 20:32:20 |
| User entered empty. | Hassan Haji (b) (4)<br>(b) (4) | 17 Sep 2020 20:05:07 |

US3742169

**Folder:** Adverse Events

**Form:** Adverse Events (1)

**Generated On:** 26 Nov 2020 11:15:04

[Persistent or significant disability or incapacity](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 01 Oct 2020 20:32:20 |
| User entered '0'    | Hassan Haji (b) (4)<br>(b) (4) | 17 Sep 2020 20:05:07 |

US3742169

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:04

[Congenital anomaly or birth defect](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 01 Oct 2020 20:32:20 |
| User entered '0'    | Hassan Haji (b) (4)<br>(b) (4) | 17 Sep 2020 20:05:07 |



US3742169

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:04

[Other medically important event](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 01 Oct 2020 20:32:20 |
| User entered '0'    | Hassan Haji (b) (4)<br>(b) (4) | 17 Sep 2020 20:05:07 |

US3742169

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:04

[Relationship to investigational product](#)

| Audit                                    | User                           | Time (GMT)           |
|------------------------------------------|--------------------------------|----------------------|
| DataPoint Verified.                      | (b) (4), (b) (6)               | 01 Oct 2020 20:32:20 |
| User entered 'Not Related (NOT RELATED)' | Hassan Haji (b) (4)<br>(b) (4) | 17 Sep 2020 20:05:07 |

US3742169

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:04

[Relationship to Study Procedure](#)

| Audit                                    | User                           | Time (GMT)           |
|------------------------------------------|--------------------------------|----------------------|
| DataPoint Verified.                      | (b) (4), (b) (6)               | 01 Oct 2020 20:32:20 |
| User entered 'Not Related (NOT RELATED)' | Hassan Haji (b) (4)<br>(b) (4) | 17 Sep 2020 20:05:07 |

US3742169

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:04

[Action taken with investigational product](#)

| Audit                                                                                  | User                | Time (GMT)           |
|----------------------------------------------------------------------------------------|---------------------|----------------------|
| DataPoint Verified.                                                                    | (b) (4), (b) (6)    | 01 Oct 2020 20:32:20 |
| User closed query 'Data is required. Please complete.' (Site from System).             | System              | 17 Sep 2020 20:05:24 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System              | 17 Sep 2020 20:05:24 |
| User entered 'None (NONE)' reason for change: Data Entry Error                         | Hassan Haji (b) (4) | 17 Sep 2020 20:05:24 |
| User opened query 'Data is required. Please complete.' (Site from System).             | System              | 17 Sep 2020 20:05:07 |
| User entered empty.                                                                    | Hassan Haji (b) (4) | 17 Sep 2020 20:05:07 |

US3742169

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:04

[None](#)

| Audit                                                | User                  | Time (GMT)           |
|------------------------------------------------------|-----------------------|----------------------|
| DataPoint Verified.                                  | (b) (4), (b) (6)      | 28 Oct 2020 15:58:47 |
| DataPoint Un-verified.                               | Kaitlin Mason (b) (4) | 21 Oct 2020 15:07:09 |
| User entered '0' reason for change: Data Entry Error | (b) (4)               | 21 Oct 2020 15:07:09 |
| DataPoint Verified.                                  | Kaitlin Mason (b) (4) | 21 Oct 2020 15:07:09 |
|                                                      | (b) (4)               |                      |
| DataPoint Verified.                                  | (b) (4), (b) (6)      | 01 Oct 2020 20:32:20 |
| User entered '1'                                     | Hassan Haji (b) (4)   | 17 Sep 2020 20:05:07 |
|                                                      | (b) (4)               |                      |

US3742169

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:04

[Concomitant Medication](#)

| Audit                                                | User                  | Time (GMT)           |
|------------------------------------------------------|-----------------------|----------------------|
| DataPoint Verified.                                  | (b) (4), (b) (6)      | 28 Oct 2020 15:58:47 |
| DataPoint Un-verified.                               | Kaitlin Mason (b) (4) | 21 Oct 2020 15:07:09 |
| User entered '1' reason for change: Data Entry Error | (b) (4)               | 21 Oct 2020 15:07:09 |
| DataPoint Verified.                                  | Kaitlin Mason (b) (4) | 21 Oct 2020 15:07:09 |
|                                                      | (b) (4)               |                      |
| DataPoint Verified.                                  | (b) (4), (b) (6)      | 01 Oct 2020 20:32:20 |
| User entered '0'                                     | Hassan Haji (b) (4)   | 17 Sep 2020 20:05:07 |
|                                                      | (b) (4)               |                      |

US3742169

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:04

[Concomitant Procedure](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 01 Oct 2020 20:32:20 |
| User entered '0'    | Hassan Haji (b) (4)<br>(b) (4) | 17 Sep 2020 20:05:07 |

**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 11:15:04**

[Outcome](#)

| Audit                                                  | User                           | Time (GMT)           |
|--------------------------------------------------------|--------------------------------|----------------------|
| DataPoint Verified.                                    | (b) (4), (b) (6)               | 01 Oct 2020 20:32:20 |
| User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' | Hassan Haji (b) (4)<br>(b) (4) | 17 Sep 2020 20:05:07 |



US3742169

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:04

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 01 Oct 2020 20:32:20 |
| User entered empty. | Hassan Haji (b) (4)<br>(b) (4) | 17 Sep 2020 20:05:07 |

US3742169

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:04

[Narrative](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 01 Oct 2020 20:32:20 |
| User entered empty. | Hassan Haji (b) (4)<br>(b) (4) | 17 Sep 2020 20:05:07 |

US3742169

**Folder:** Adverse Events

**Form:** Adverse Events (1)

**Generated On:** 26 Nov 2020 11:15:04

Serious Adverse Event Derived (CSA Programming Field Only)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '0' | System | 17 Sep 2020 20:05:07 |

US3742169

**Folder:** Adverse Events

**Form:** Adverse Events (1)

**Generated On:** 26 Nov 2020 11:15:04

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '0' | System | 17 Sep 2020 20:05:07 |

US3742169

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:15:04

[AEID](#)

| Audit                                                 | User             | Time (GMT)           |
|-------------------------------------------------------|------------------|----------------------|
| DataPoint Verified.                                   | (b) (4), (b) (6) | 14 Oct 2020 20:06:01 |
| Reviewed for Safety.                                  | (b) (4), (b) (6) | 05 Oct 2020 13:32:19 |
| User entered<br>'USA-US127-2020-mRNA-1273-P301000003' | System           | 05 Oct 2020 13:32:04 |
| User entered 'New'                                    | (b) (4), (b) (6) | 05 Oct 2020 13:32:04 |

US3742169

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:15:04

[Adverse event](#)

| Audit                                                                                                                                                                                                                                                                                                 | User                  | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|----------------------|
| User closed query 'Per DM CLR: Please review AE and please update to specify the location of Rheumatoid Arthritis. Please update and reconcile with applicable eCRFs so there would be an appropriate match. Otherwise, clarify.' (Site from DM).                                                     | (b) (4), (b) (6)      | 10 Nov 2020 21:41:24 |
| Query 'Per DM CLR: Please review AE and please update to specify the location of Rheumatoid Arthritis. Please update and reconcile with applicable eCRFs so there would be an appropriate match. Otherwise, clarify.' answered with 'Specific location not necessary per PPD monitor' (Site from DM). | Kaitlin Mason (b) (4) | 09 Nov 2020 20:00:36 |
| User opened query 'Per DM CLR: Please review AE and please update to specify the location of Rheumatoid Arthritis. Please update and reconcile with applicable eCRFs so there would be an appropriate match. Otherwise, clarify.' (Site from DM).                                                     | (b) (4), (b) (6)      | 02 Nov 2020 14:20:38 |
| DataPoint Verified.                                                                                                                                                                                                                                                                                   | (b) (4), (b) (6)      | 14 Oct 2020 20:06:01 |
| User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Rheumatoid arthropathies, PT: Rheumatoid arthritis, LLT: Rheumatoid arthritis - version MedDRA\23.0.                                                                                       | Coder Import (b) (4)  | 03 Oct 2020 15:11:43 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.                                                                                                                                                                                                           | Coder Import (b) (4)  | 03 Oct 2020 15:11:43 |
| Data point term sent to Coder                                                                                                                                                                                                                                                                         | System                | 03 Oct 2020 15:11:34 |
| DataPoint Un-verified.                                                                                                                                                                                                                                                                                | (b) (4), (b) (6)      | 03 Oct 2020 15:10:36 |
| Coding entries removed.                                                                                                                                                                                                                                                                               | (b) (4), (b) (6)      | 03 Oct 2020 15:10:36 |
| User entered 'RHEUMATOID ARTHRITIS' reason for change: New Information                                                                                                                                                                                                                                | (b) (4), (b) (6)      | 03 Oct 2020 15:10:36 |
| DataPoint Verified.                                                                                                                                                                                                                                                                                   | (b) (4), (b) (6)      | 01 Oct 2020 20:32:20 |
| User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related signs and symptoms, PT: Arthralgia, LLT: Joint pain - version MedDRA\23.0.                                                                                                   | Coder Import (b) (4)  | 25 Sep 2020 16:53:57 |

US3742169

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:15:04

[Adverse event](#)

| Audit                                             | User                 | Time (GMT)           |
|---------------------------------------------------|----------------------|----------------------|
| User coded data point as Term Coded data point by | Coder Import (b) (4) | 25 Sep 2020 16:53:57 |
| User: Coder System - version MedDRA\\23.0.        | (b) (4)              |                      |
| Data point term sent to Coder                     | System               | 25 Sep 2020 16:03:25 |
| User entered 'JOINT PAIN'                         | (b) (4), (b) (6)     | 25 Sep 2020 16:03:14 |
|                                                   |                      |                      |

US3742169

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:15:04

[Was this a medically-attended AE?](#)

| Audit                                                                                  | User             | Time (GMT)           |
|----------------------------------------------------------------------------------------|------------------|----------------------|
| DataPoint Verified.                                                                    | (b) (4), (b) (6) | 14 Oct 2020 20:06:01 |
| User closed query 'Data is required. Please complete.' (Site from System).             | System           | 03 Oct 2020 15:10:36 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System           | 03 Oct 2020 15:10:36 |
| DataPoint Un-verified.                                                                 | (b) (4), (b) (6) | 03 Oct 2020 15:10:36 |
| User entered 'Yes (Y)' reason for change: New Information                              | (b) (4), (b) (6) | 03 Oct 2020 15:10:36 |
| DataPoint Verified.                                                                    | (b) (4), (b) (6) | 01 Oct 2020 20:33:10 |
| DataPoint Un-verified.                                                                 | (b) (4), (b) (6) | 01 Oct 2020 20:32:23 |
| DataPoint Verified.                                                                    | (b) (4), (b) (6) | 01 Oct 2020 20:32:20 |
| User opened query 'Data is required. Please complete.' (Site from System).             | System           | 25 Sep 2020 16:03:14 |
| User entered empty.                                                                    | (b) (4), (b) (6) | 25 Sep 2020 16:03:14 |



US3742169

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:15:04

[Was this a Solicited Adverse Reaction?](#)

| Audit                                                                                  | User                  | Time (GMT)           |
|----------------------------------------------------------------------------------------|-----------------------|----------------------|
| DataPoint Verified.                                                                    | (b) (4), (b) (6)      | 01 Oct 2020 20:32:20 |
| User closed query 'Data is required. Please complete.' (Site from System).             | System                | 28 Sep 2020 14:46:52 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System                | 28 Sep 2020 14:46:52 |
| User entered 'No (N)' reason for change: Data Entry Error                              | Kaitlin Mason (b) (4) | 28 Sep 2020 14:46:52 |
| User opened query 'Data is required. Please complete.' (Site from System).             | System                | 25 Sep 2020 16:03:14 |
| User entered empty.                                                                    | (b) (4), (b) (6)      | 25 Sep 2020 16:03:14 |

US3742169

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:15:04

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit                                                                                  | User                  | Time (GMT)           |
|----------------------------------------------------------------------------------------|-----------------------|----------------------|
| DataPoint Verified.                                                                    | (b) (4), (b) (6)      | 01 Oct 2020 20:32:20 |
| User closed query 'Data is required. Please complete.' (Site from System).             | System                | 28 Sep 2020 14:46:52 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System                | 28 Sep 2020 14:46:52 |
| User entered 'No (N)' reason for change: Data Entry Error                              | Kaitlin Mason (b) (4) | 28 Sep 2020 14:46:52 |
| User opened query 'Data is required. Please complete.' (Site from System).             | System                | 25 Sep 2020 16:03:14 |
| User entered empty.                                                                    | (b) (4), (b) (6)      | 25 Sep 2020 16:03:14 |

US3742169

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:15:04

Start date (dd MMM yyyy)

| Audit                                                                                                                                                                        | User                     | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|----------------------|
| User closed query 'PV Query: Please consider updating start date to date of onset of symptoms.' (Site from Safety).                                                          | (b) (4), (b) (6)         | 15 Oct 2020 12:40:58 |
| DataPoint Verified.                                                                                                                                                          | (b) (4), (b) (6)         | 14 Oct 2020 20:06:01 |
| Query 'PV Query: Please consider updating start date to date of onset of symptoms.' answered with 'This the earliest day joint pains appeared in diary.' (Site from Safety). | Milagritos Tapia (b) (4) | 14 Oct 2020 16:58:58 |
| DataPoint Un-verified.                                                                                                                                                       | Milagritos Tapia (b) (4) | 14 Oct 2020 16:57:47 |
| User entered '31 Aug 2020' reason for change: Per Query Resolution                                                                                                           | Milagritos Tapia (b) (4) | 14 Oct 2020 16:57:47 |
| User opened query 'PV Query: Please consider updating start date to date of onset of symptoms.' (Site from Safety).                                                          | (b) (4), (b) (6)         | 13 Oct 2020 20:26:01 |
| DataPoint Verified.                                                                                                                                                          | (b) (4), (b) (6)         | 01 Oct 2020 20:32:20 |
| User entered '13 Sep 2020'                                                                                                                                                   | (b) (4), (b) (6)         | 25 Sep 2020 16:03:14 |

US3742169

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:15:04

Start time (00:00-23:59)

| Audit                                                                     | User                     | Time (GMT)           |
|---------------------------------------------------------------------------|--------------------------|----------------------|
| DataPoint Verified.                                                       | (b) (4), (b) (6)         | 28 Oct 2020 15:58:33 |
| User closed query 'Data is required. Please provide.' (Site from System). | System                   | 15 Oct 2020 23:58:38 |
| User entered '23:00' reason for change: Per Query Resolution              | Milagritos Tapia (b) (4) | 15 Oct 2020 23:58:38 |
| DataPoint Un-verified.                                                    | (b) (4), (b) (6)         | 14 Oct 2020 20:06:53 |
| User opened query 'Data is required. Please provide.' (Site from System). | System                   | 14 Oct 2020 16:57:47 |
| DataPoint Verified.                                                       | (b) (4), (b) (6)         | 01 Oct 2020 20:32:20 |
| User entered empty.                                                       | (b) (4), (b) (6)         | 25 Sep 2020 16:03:14 |

US3742169

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:15:04

[AE start date and time \(derived\)](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '31 Aug 2020 23:00' | System | 15 Oct 2020 23:58:38 |
| User entered empty.              | System | 25 Sep 2020 16:03:14 |

US3742169

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:15:04

[Ongoing?](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 01 Oct 2020 20:32:20 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 25 Sep 2020 16:03:14 |

US3742169

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:15:04

If not Ongoing, end date (dd MMM yyyy)

| Audit                                                                                                                                                                                                                                   | User                  | Time (GMT)           |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|----------------------|
| User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).                             | (b) (4), (b) (6)      | 10 Nov 2020 14:10:50 |
| Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'not expected to resolve' (Site from Safety). | Kaitlin Mason (b) (4) | 09 Nov 2020 20:00:08 |
| DataPoint Verified.                                                                                                                                                                                                                     | (b) (4), (b) (6)      | 28 Oct 2020 15:58:33 |
| DataPoint Un-verified.                                                                                                                                                                                                                  | (b) (4), (b) (6)      | 14 Oct 2020 20:07:14 |
| User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).                             | (b) (4), (b) (6)      | 13 Oct 2020 20:25:32 |
| DataPoint Verified.                                                                                                                                                                                                                     | (b) (4), (b) (6)      | 01 Oct 2020 20:32:20 |
| User entered empty.                                                                                                                                                                                                                     | (b) (4), (b) (6)      | 25 Sep 2020 16:03:14 |

US3742169

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:15:04

End time (00:00-23:59)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 20:32:20 |
| User entered empty. | (b) (4), (b) (6) | 25 Sep 2020 16:03:14 |



US3742169

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:15:04

[AE End Date and Time \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 25 Sep 2020 16:03:14 |

US3742169

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:15:04

[Severity](#)

| Audit                                              | User             | Time (GMT)           |
|----------------------------------------------------|------------------|----------------------|
| DataPoint Verified.                                | (b) (4), (b) (6) | 01 Oct 2020 20:32:20 |
| User entered 'Grade 2/Moderate (Grade 2/Moderate)' | (b) (4), (b) (6) | 25 Sep 2020 16:03:14 |

US3742169

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:15:04

[Is the adverse event serious?](#)

| Audit                                                                                  | User             | Time (GMT)           |
|----------------------------------------------------------------------------------------|------------------|----------------------|
| DataPoint Verified.                                                                    | (b) (4), (b) (6) | 14 Oct 2020 20:06:01 |
| User closed query 'Data is required. Please complete.' (Site from System).             | System           | 03 Oct 2020 15:10:36 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System           | 03 Oct 2020 15:10:36 |
| DataPoint Un-verified.                                                                 | (b) (4), (b) (6) | 03 Oct 2020 15:10:36 |
| User entered 'Yes (Y)' reason for change: New Information                              | (b) (4), (b) (6) | 03 Oct 2020 15:10:36 |
| DataPoint Verified.                                                                    | (b) (4), (b) (6) | 01 Oct 2020 20:33:10 |
| DataPoint Un-verified.                                                                 | (b) (4), (b) (6) | 01 Oct 2020 20:32:41 |
| DataPoint Verified.                                                                    | (b) (4), (b) (6) | 01 Oct 2020 20:32:20 |
| User opened query 'Data is required. Please complete.' (Site from System).             | System           | 25 Sep 2020 16:03:14 |
| User entered empty.                                                                    | (b) (4), (b) (6) | 25 Sep 2020 16:03:14 |

US3742169

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:15:04

[Death](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 20:32:20 |
| User entered '0'    | (b) (4), (b) (6) | 25 Sep 2020 16:03:14 |

US3742169

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:15:04

[Life threatening](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 20:32:20 |
| User entered '0'    | (b) (4), (b) (6) | 25 Sep 2020 16:03:14 |

US3742169

**Folder:** Adverse Events

**Form:** Adverse Events (2)

**Generated On:** 26 Nov 2020 11:15:04

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 20:32:20 |
| User entered '0'    | (b) (4), (b) (6) | 25 Sep 2020 16:03:14 |

US3742169

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:15:04

[Hospital Admission Date \(dd MMM yyyy\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 20:32:20 |
| User entered empty. | (b) (4), (b) (6) | 25 Sep 2020 16:03:14 |

US3742169

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:15:04

Hospital Discharge Date (*dd MMM yyyy*)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 20:32:20 |
| User entered empty. | (b) (4), (b) (6) | 25 Sep 2020 16:03:14 |



US3742169

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:15:04

[Admitted to ICU?](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 20:32:20 |
| User entered empty. | (b) (4), (b) (6) | 25 Sep 2020 16:03:14 |

US3742169

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:15:04

[Number of Days in ICU](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 20:32:20 |
| User entered empty. | (b) (4), (b) (6) | 25 Sep 2020 16:03:14 |

US3742169

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:15:04

[Persistent or significant disability or incapacity](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 20:32:20 |
| User entered '0'    | (b) (4), (b) (6) | 25 Sep 2020 16:03:14 |

US3742169

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:15:04

[Congenital anomaly or birth defect](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 20:32:20 |
| User entered '0'    | (b) (4), (b) (6) | 25 Sep 2020 16:03:14 |

US3742169

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:15:04

[Other medically important event](#)

| Audit                                               | User             | Time (GMT)           |
|-----------------------------------------------------|------------------|----------------------|
| DataPoint Verified.                                 | (b) (4), (b) (6) | 14 Oct 2020 20:06:01 |
| DataPoint Un-verified.                              | (b) (4), (b) (6) | 03 Oct 2020 15:10:36 |
| User entered '1' reason for change: New Information | (b) (4), (b) (6) | 03 Oct 2020 15:10:36 |
| DataPoint Verified.                                 | (b) (4), (b) (6) | 01 Oct 2020 20:32:20 |
| User entered '0'                                    | (b) (4), (b) (6) | 25 Sep 2020 16:03:14 |

US3742169

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:15:04

[Relationship to investigational product](#)

| Audit                                                                                  | User             | Time (GMT)           |
|----------------------------------------------------------------------------------------|------------------|----------------------|
| DataPoint Verified.                                                                    | (b) (4), (b) (6) | 14 Oct 2020 20:06:01 |
| User closed query 'Data is required. Please complete.' (Site from System).             | System           | 03 Oct 2020 15:10:36 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System           | 03 Oct 2020 15:10:36 |
| DataPoint Un-verified.                                                                 | (b) (4), (b) (6) | 03 Oct 2020 15:10:36 |
| User entered 'Related (RELATED)' reason for change: New Information                    | (b) (4), (b) (6) | 03 Oct 2020 15:10:36 |
| DataPoint Verified.                                                                    | (b) (4), (b) (6) | 01 Oct 2020 20:32:20 |
| User opened query 'Data is required. Please complete.' (Site from System).             | System           | 25 Sep 2020 16:03:14 |
| User entered empty.                                                                    | (b) (4), (b) (6) | 25 Sep 2020 16:03:14 |

US3742169

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:15:04

[Relationship to Study Procedure](#)

| Audit                                                                                  | User             | Time (GMT)           |
|----------------------------------------------------------------------------------------|------------------|----------------------|
| DataPoint Verified.                                                                    | (b) (4), (b) (6) | 14 Oct 2020 20:06:01 |
| User closed query 'Data is required. Please complete.' (Site from System).             | System           | 03 Oct 2020 15:10:36 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System           | 03 Oct 2020 15:10:36 |
| DataPoint Un-verified.                                                                 | (b) (4), (b) (6) | 03 Oct 2020 15:10:36 |
| User entered 'Not Related (NOT RELATED)' reason for change: New Information            | (b) (4), (b) (6) | 03 Oct 2020 15:10:36 |
| DataPoint Verified.                                                                    | (b) (4), (b) (6) | 01 Oct 2020 20:32:20 |
| User opened query 'Data is required. Please complete.' (Site from System).             | System           | 25 Sep 2020 16:03:14 |
| User entered empty.                                                                    | (b) (4), (b) (6) | 25 Sep 2020 16:03:14 |

US3742169

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:15:04

Action taken with investigational product

| Audit                                                                                           | User             | Time (GMT)           |
|-------------------------------------------------------------------------------------------------|------------------|----------------------|
| DataPoint Verified.                                                                             | (b) (4), (b) (6) | 14 Oct 2020 20:06:01 |
| User closed query 'Data is required. Please complete.' (Site from System).                      | System           | 03 Oct 2020 15:10:36 |
| Query 'Data is required. Please complete.' answered by data change (Site from System).          | System           | 03 Oct 2020 15:10:36 |
| DataPoint Un-verified.                                                                          | (b) (4), (b) (6) | 03 Oct 2020 15:10:36 |
| User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: New Information | (b) (4), (b) (6) | 03 Oct 2020 15:10:36 |
| DataPoint Verified.                                                                             | (b) (4), (b) (6) | 01 Oct 2020 20:32:20 |
| User opened query 'Data is required. Please complete.' (Site from System).                      | System           | 25 Sep 2020 16:03:14 |
| User entered empty.                                                                             | (b) (4), (b) (6) | 25 Sep 2020 16:03:14 |



US3742169

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:15:04

None

| Audit                                                                                                                                                                                                                                                 | User                  | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|----------------------|
| DataPoint Verified.                                                                                                                                                                                                                                   | (b) (4), (b) (6)      | 17 Nov 2020 19:13:16 |
| User closed query 'Per DM CLR: Other Action Taken = None. However, there is a recorded ConMed that match this AE during this time frame. Please review and update Other Action Taken as appropriate. Otherwise, clarify.' (Site from DM).             | (b) (4), (b) (6)      | 10 Nov 2020 21:50:43 |
| Query 'Per DM CLR: Other Action Taken = None. However, there is a recorded ConMed that match this AE during this time frame. Please review and update Other Action Taken as appropriate. Otherwise, clarify.' answered with 'updated' (Site from DM). | Kaitlin Mason (b) (4) | 09 Nov 2020 19:59:54 |
| DataPoint Un-verified.                                                                                                                                                                                                                                | (b) (4)               | 09 Nov 2020 19:58:05 |
| User entered '0' reason for change: Data Entry Error                                                                                                                                                                                                  | Kaitlin Mason (b) (4) | 09 Nov 2020 19:58:05 |
| User opened query 'Per DM CLR: Other Action Taken = None. However, there is a recorded ConMed that match this AE during this time frame. Please review and update Other Action Taken as appropriate. Otherwise, clarify.' (Site from DM).             | (b) (4), (b) (6)      | 02 Nov 2020 14:21:24 |
| DataPoint Verified.                                                                                                                                                                                                                                   | (b) (4), (b) (6)      | 14 Oct 2020 20:06:01 |
| User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).                                                                                                                    | System                | 03 Oct 2020 15:10:36 |
| DataPoint Un-verified.                                                                                                                                                                                                                                | (b) (4), (b) (6)      | 03 Oct 2020 15:10:36 |
| User entered '1' reason for change: Data Entry Error                                                                                                                                                                                                  | (b) (4), (b) (6)      | 03 Oct 2020 15:10:36 |
| DataPoint Verified.                                                                                                                                                                                                                                   | (b) (4), (b) (6)      | 01 Oct 2020 20:32:20 |
| User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).                                                                                                                    | System                | 25 Sep 2020 16:03:14 |
| User entered '0'                                                                                                                                                                                                                                      | (b) (4), (b) (6)      | 25 Sep 2020 16:03:14 |

US3742169

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:15:04

[Concomitant Medication](#)

| Audit                                                | User                  | Time (GMT)           |
|------------------------------------------------------|-----------------------|----------------------|
| DataPoint Verified.                                  | (b) (4), (b) (6)      | 17 Nov 2020 19:13:16 |
| DataPoint Un-verified.                               | Kaitlin Mason (b) (4) | 09 Nov 2020 19:58:05 |
| User entered '1' reason for change: Data Entry Error | (b) (4)               | 09 Nov 2020 19:58:05 |
| DataPoint Verified.                                  | Kaitlin Mason (b) (4) | 01 Oct 2020 20:32:20 |
| User entered '0'                                     | (b) (4), (b) (6)      | 25 Sep 2020 16:03:14 |

US3742169

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:15:04

[Concomitant Procedure](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 20:32:20 |
| User entered '0'    | (b) (4), (b) (6) | 25 Sep 2020 16:03:14 |

US3742169

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:15:04

[Outcome](#)

| Audit                                                                                                                                                                                                                                                                | User                  | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|----------------------|
| User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).                             | (b) (4), (b) (6)      | 10 Nov 2020 14:10:57 |
| Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'Not expected to resolve' (Site from Safety). | Kaitlin Mason (b) (4) | 09 Nov 2020 19:59:47 |
| DataPoint Verified.                                                                                                                                                                                                                                                  | (b) (4), (b) (6)      | 14 Oct 2020 20:06:01 |
| User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).                             | (b) (4), (b) (6)      | 13 Oct 2020 20:25:47 |
| User closed query 'Data is required. Please complete.' (Site from System).                                                                                                                                                                                           | System                | 03 Oct 2020 15:10:36 |
| Query 'Data is required. Please complete.' answered by data change (Site from System).                                                                                                                                                                               | System                | 03 Oct 2020 15:10:36 |
| DataPoint Un-verified.                                                                                                                                                                                                                                               | (b) (4), (b) (6)      | 03 Oct 2020 15:10:36 |
| User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: New Information                                                                                                                                                            | (b) (4), (b) (6)      | 03 Oct 2020 15:10:36 |
| DataPoint Verified.                                                                                                                                                                                                                                                  | (b) (4), (b) (6)      | 01 Oct 2020 20:32:20 |
| User opened query 'Data is required. Please complete.' (Site from System).                                                                                                                                                                                           | System                | 25 Sep 2020 16:03:14 |
| User entered empty.                                                                                                                                                                                                                                                  | (b) (4), (b) (6)      | 25 Sep 2020 16:03:14 |

US3742169

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:15:04

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 20:32:20 |
| User entered empty. | (b) (4), (b) (6) | 25 Sep 2020 16:03:14 |

US3742169

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:15:04

[Narrative](#)

| Audit                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | User                             | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------|----------------------|
| User closed query 'PV query: It was reported that patient had no medical history of joint pain/swelling, while also reporting hip pain in January 2020. Please clarify and provide the etiology for the ongoing hip pain which originated in January 2020.' (Site from Safety).                                                                                                                                                                                           | (b) (4), (b) (6)                 | 23 Nov 2020 15:23:47 |
| User closed query 'PV Query: Rheumatology notes received were from visit on 9/29 with plans to follow-up in 2 weeks. Please provide follow-up Rheumatology office visit notes and any diagnostic exams/laboratory results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent.' (Site from Safety).                                                               | (b) (4), (b) (6)                 | 23 Nov 2020 15:23:45 |
| Query 'PV query: It was reported that patient had no medical history of joint pain/swelling, while also reporting hip pain in January 2020. Please clarify and provide the etiology for the ongoing hip pain which originated in January 2020.' answered with 'Called participant to clarify hip pain - stated that it is more of a left outer thigh pain that began with wearing an ill fitting surgical boot. Medical history updated accordingly ' (Site from Safety). | Kaitlin Mason (b) (4)<br>(b) (4) | 20 Nov 2020 18:01:20 |
| Query 'PV Query: Rheumatology notes received were from visit on 9/29 with plans to follow-up in 2 weeks. Please provide follow-up Rheumatology office visit notes and any diagnostic exams/laboratory results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent.' answered with 'Follow up notes sent to email address above' (Site from Safety).               | Kaitlin Mason (b) (4)<br>(b) (4) | 20 Nov 2020 17:04:52 |
| User opened query 'PV query: It was reported that patient had no medical history of joint pain/swelling, while also reporting hip pain in January 2020. Please clarify and provide the etiology for the ongoing hip pain which originated in January 2020.' (Site from Safety).                                                                                                                                                                                           | (b) (4), (b) (6)                 | 19 Nov 2020 23:13:22 |

US3742169

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:15:04

[Narrative](#)

| Audit                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | User                             | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------|----------------------|
| User opened query 'PV Query: Rheumatology notes received were from visit on 9/29 with plans to follow-up in 2 weeks. Please provide follow-up Rheumatology office visit notes and any diagnostic exams/laboratory results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent.' (Site from Safety).                                                                                            | (b) (4), (b) (6)                 | 19 Nov 2020 23:13:12 |
| User closed query 'PV Query: Rheumatology notes received were from visit on 9/29 with plans to follow-up in 2 weeks. Please provide follow-up Rheumatology office visit notes and any diagnostic exams/laboratory results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent.' (Site from Safety).                                                                                            | (b) (4), (b) (6)                 | 19 Nov 2020 17:43:14 |
| Query 'PV Query: Rheumatology notes received were from visit on 9/29 with plans to follow-up in 2 weeks. Please provide follow-up Rheumatology office visit notes and any diagnostic exams/laboratory results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent.' answered with 'Office visit notes sent via email November 18th at 10:44 to Safety_Moderna@iqvia.com. ' (Site from Safety). | Kaitlin Mason (b) (4)<br>(b) (4) | 18 Nov 2020 15:44:32 |
| User opened query 'PV Query: Rheumatology notes received were from visit on 9/29 with plans to follow-up in 2 weeks. Please provide follow-up Rheumatology office visit notes and any diagnostic exams/laboratory results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent.' (Site from Safety).                                                                                            | (b) (4), (b) (6)                 | 29 Oct 2020 18:35:49 |

US3742169

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:15:04

[Narrative](#)

| Audit                                                                                                                                                                                                                                                                                                                                                             | User                             | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------|----------------------|
| User closed query 'PV Query: Please provide office visit notes and any diagnostic exams/laboratory results from the additional planned follow-up with Rheumatology with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent.' (Site from Safety).              | (b) (4), (b) (6)                 | 29 Oct 2020 17:12:23 |
| Query 'PV Query: Please provide office visit notes and any diagnostic exams/laboratory results from the additional planned follow-up with Rheumatology with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent.' answered with 'PROVIDED' (Site from Safety). | Kaitlin Mason (b) (4)<br>(b) (4) | 28 Oct 2020 13:36:07 |
| User opened query 'PV Query: Please provide office visit notes and any diagnostic exams/laboratory results from the additional planned follow-up with Rheumatology with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent.' (Site from Safety).              | (b) (4), (b) (6)                 | 23 Oct 2020 21:28:11 |
| User closed query 'PV Query: Please clarify if subject had joint pain or swelling in the (recent) past prior to the vaccine.' (Site from Safety).                                                                                                                                                                                                                 | (b) (4), (b) (6)                 | 15 Oct 2020 12:41:26 |
| User closed query 'PV Query: Please provide the dates the rheumatoid factor and anti-CCP AB tests were performed.' (Site from Safety).                                                                                                                                                                                                                            | (b) (4), (b) (6)                 | 15 Oct 2020 12:41:24 |
| User closed query 'PV Query: Please report the treatment received by the subject, including any procedures.' (Site from Safety).                                                                                                                                                                                                                                  | (b) (4), (b) (6)                 | 15 Oct 2020 12:41:22 |
| User closed query 'PV Query: Please report if there were any factors that precipitated the event.' (Site from Safety).                                                                                                                                                                                                                                            | (b) (4), (b) (6)                 | 15 Oct 2020 12:41:21 |
| User closed query 'PV Query: Please provide results of any diagnostic studies done to evaluate the event (lab testing, imaging, biopsies, etc).' (Site from Safety).                                                                                                                                                                                              | (b) (4), (b) (6)                 | 15 Oct 2020 12:41:19 |



US3742169

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:15:04

[Narrative](#)

| Audit                                                                                                                                                                                                                                                                                                                                   | User                                | Time (GMT)           |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|----------------------|
| User closed query 'PV Query: Please provide rheumatology consult notes with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).                                       | (b) (4), (b) (6)                    | 15 Oct 2020 12:41:15 |
| User closed query 'PV Query: Describe the clinical course of the event, including signs and symptoms.' (Site from Safety).                                                                                                                                                                                                              | (b) (4), (b) (6)                    | 15 Oct 2020 12:41:13 |
| User closed query 'PV Query: Please indicate any risk factors the subject had for the development of the event, please provide relevant medical history including history of autoimmune disorders (MS, lupus, RA, IBD, psoriasis, etc) with onset date(s), severity, treatment and relevant details.' (Site from Safety).               | (b) (4), (b) (6)                    | 15 Oct 2020 12:41:10 |
| DataPoint Verified.                                                                                                                                                                                                                                                                                                                     | (b) (4), (b) (6)                    | 14 Oct 2020 20:06:01 |
| Query 'PV Query: Please provide rheumatology consult notes with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' answered with 'The note has been sent via email.' (Site from Safety). | Milagritos Tapia (b) (4)<br>(b) (4) | 14 Oct 2020 17:49:07 |
| Query 'PV Query: Please provide results of any diagnostic studies done to evaluate the event (lab testing, imaging, biopsies, etc).' answered with 'All results are provided in the consult note that has been sent.' (Site from Safety).                                                                                               | Milagritos Tapia (b) (4)<br>(b) (4) | 14 Oct 2020 17:48:26 |
| Query 'PV Query: Please report the treatment received by the subject, including any procedures.' answered with 'The participant took tylenol to treat the pain.' (Site from Safety).                                                                                                                                                    | Milagritos Tapia (b) (4)<br>(b) (4) | 14 Oct 2020 17:47:48 |
| Query 'PV Query: Please provide the dates the rheumatoid factor and anti-CCP AB tests were performed.' answered with 'These were collected on 25 September 2020.' (Site from Safety).                                                                                                                                                   | Milagritos Tapia (b) (4)<br>(b) (4) | 14 Oct 2020 17:46:50 |

US3742169

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:15:04

[Narrative](#)

| Audit                                                                                                                                                                                                                                                                                                                                                                                               | User                                 | Time (GMT)           |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------|----------------------|
| Query 'PV Query: Please clarify if subject had joint pain or swelling in the (recent) past prior to the vaccine.' answered with 'Denied join pain/swelling in the past' (Site from Safety).                                                                                                                                                                                                         | Kaitlin Mason (b) (4)<br>(b) (4)     | 14 Oct 2020 14:15:02 |
| Query 'PV Query: Please report if there were any factors that precipitated the event.' answered with 'No precipitating factors outside of vaccination ' (Site from Safety).                                                                                                                                                                                                                         | Kaitlin Mason (b) (4)<br>(b) (4)     | 14 Oct 2020 14:14:38 |
| Query 'PV Query: Describe the clinical course of the event, including signs and symptoms.' answered with 'Included in narrative ' (Site from Safety).                                                                                                                                                                                                                                               | Kaitlin Mason (b) (4)<br>(b) (4)     | 14 Oct 2020 14:14:22 |
| Query 'PV Query: Please indicate any risk factors the subject had for the development of the event, please provide relevant medical history including history of autoimmune disorders (MS, lupus, RA, IBD, psoriasis, etc) with onset date(s), severity, treatment and relevant details.' answered with 'No history of risk factors or precipitating conditions. MH up to date' (Site from Safety). | Kaitlin Mason (b) (4)<br>(b) (4)     | 14 Oct 2020 14:13:52 |
| User opened query 'PV Query: Please clarify if subject had joint pain or swelling in the (recent) past prior to the vaccine.' (Site from Safety).                                                                                                                                                                                                                                                   | (b) (4), (b) (6)<br>(b) (4), (b) (6) | 13 Oct 2020 20:26:27 |
| User opened query 'PV Query: Please provide the dates the rheumatoid factor and anti-CCP AB tests were performed.' (Site from Safety).                                                                                                                                                                                                                                                              | (b) (4), (b) (6)<br>(b) (4), (b) (6) | 13 Oct 2020 20:24:29 |
| User opened query 'PV Query: Please report the treatment received by the subject, including any procedures.' (Site from Safety).                                                                                                                                                                                                                                                                    | (b) (4), (b) (6)<br>(b) (4), (b) (6) | 13 Oct 2020 20:24:19 |
| User opened query 'PV Query: Please report if there were any factors that precipitated the event.' (Site from Safety).                                                                                                                                                                                                                                                                              | (b) (4), (b) (6)<br>(b) (4), (b) (6) | 13 Oct 2020 20:24:07 |
| User opened query 'PV Query: Please provide results of any diagnostic studies done to evaluate the event (lab testing, imaging, biopsies, etc).' (Site from Safety).                                                                                                                                                                                                                                | (b) (4), (b) (6)<br>(b) (4), (b) (6) | 13 Oct 2020 20:23:58 |
| User opened query 'PV Query: Describe the clinical course of the event, including signs and symptoms.' (Site from Safety).                                                                                                                                                                                                                                                                          | (b) (4), (b) (6)<br>(b) (4), (b) (6) | 13 Oct 2020 20:23:48 |

US3742169

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:15:04

[Narrative](#)

| Audit                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | User             | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| User opened query 'PV Query: Please provide rheumatology consult notes with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | (b) (4), (b) (6) | 13 Oct 2020 20:23:38 |
| User opened query 'PV Query: Please indicate any risk factors the subject had for the development of the event, please provide relevant medical history including history of autoimmune disorders (MS, lupus, RA, IBD, psoriasis, etc) with onset date(s), severity, treatment and relevant details.' (Site from Safety).                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | (b) (4), (b) (6) | 13 Oct 2020 20:23:27 |
| DataPoint Un-verified.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | (b) (4), (b) (6) | 03 Oct 2020 15:10:36 |
| User entered 'After first vaccination, he reported in the e-diary muscle and joint ache/pain through day 7. Muscle and joint ache/pain started again on Sunday the 13th of September, but was doing better by time of the Day 15 phone call on the 16th of September. Later that day, the joint ache and pain started again and continued. It was improved with Tylenol which he stopped taking on the 24th of September. He also experienced some tinnitus, insomnia and constipation post vaccination. On 9/29 he was seen by a rheumatologist who diagnosed him with rheumatoid arthritis. Significant laboratory results returned on 02 October 2020 and include rheumatoid factor 62.5 IU/ml (normal 0-13) and anti-CCP Ab >250 units (normal <20).' reason for change: New Information | (b) (4), (b) (6) | 03 Oct 2020 15:10:36 |
| DataPoint Verified.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | (b) (4), (b) (6) | 01 Oct 2020 20:32:20 |
| User entered empty.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | (b) (4), (b) (6) | 25 Sep 2020 16:03:14 |

US3742169

**Folder:** Adverse Events

**Form:** Adverse Events (2)

**Generated On:** 26 Nov 2020 11:15:04

Serious Adverse Event Derived (CSA Programming Field Only)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 03 Oct 2020 15:10:36 |

US3742169

**Folder:** Adverse Events

**Form:** Adverse Events (2)

**Generated On:** 26 Nov 2020 11:15:04

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 03 Oct 2020 15:10:36 |

US3742169

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:15:04

[Adverse event](#)

| Audit                                                                                                                                                                                                 | User                 | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|----------------------|
| DataPoint Verified.                                                                                                                                                                                   | (b) (4), (b) (6)     | 01 Oct 2020 20:32:20 |
| User coded data point as SOC: Ear and labyrinth disorders, HLGT: Inner ear and VIIIth cranial nerve disorders, HLT: Inner ear signs and symptoms, PT: Tinnitus, LLT: Tinnitus - version MedDRA\\23.0. | Coder Import (b) (4) | 25 Sep 2020 16:54:00 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.                                                                                                          | (b) (4)              | 25 Sep 2020 16:54:00 |
| Data point term sent to Coder                                                                                                                                                                         | System               | 25 Sep 2020 16:04:26 |
| User entered 'TINNITUS'                                                                                                                                                                               | (b) (4), (b) (6)     | 25 Sep 2020 16:04:11 |

US3742169

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:15:04

[Was this a medically-attended AE?](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 01 Oct 2020 20:32:20 |
| User entered 'No (N)' | (b) (4), (b) (6) | 25 Sep 2020 16:04:11 |

US3742169

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:15:04

[Was this a Solicited Adverse Reaction?](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 01 Oct 2020 20:32:20 |
| User entered 'No (N)' | (b) (4), (b) (6) | 25 Sep 2020 16:04:11 |



US3742169

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:15:04

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit                                                                                  | User             | Time (GMT)           |
|----------------------------------------------------------------------------------------|------------------|----------------------|
| DataPoint Verified.                                                                    | (b) (4), (b) (6) | 01 Oct 2020 20:32:20 |
| User closed query 'Data is required. Please complete.' (Site from System).             | System           | 25 Sep 2020 16:06:29 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System           | 25 Sep 2020 16:06:29 |
| User entered 'No (N)' reason for change: Data Entry Error                              | (b) (4), (b) (6) | 25 Sep 2020 16:06:29 |
| User opened query 'Data is required. Please complete.' (Site from System).             | System           | 25 Sep 2020 16:04:11 |
| User entered empty.                                                                    | (b) (4), (b) (6) | 25 Sep 2020 16:04:11 |

US3742169

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:15:04

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 01 Oct 2020 20:32:20 |
| User entered '20 Sep 2020' | (b) (4), (b) (6) | 25 Sep 2020 16:04:11 |

US3742169

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:15:04

[Start time \(00:00-23:59\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 20:32:20 |
| User entered empty. | (b) (4), (b) (6) | 25 Sep 2020 16:04:11 |

US3742169

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:15:04

[AE start date and time \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 25 Sep 2020 16:04:11 |

US3742169

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:15:04

[Ongoing?](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 01 Oct 2020 20:32:20 |
| User entered 'No (N)' | (b) (4), (b) (6) | 25 Sep 2020 16:04:11 |

US3742169

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:15:04

If not Ongoing, end date (dd MMM yyyy)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 01 Oct 2020 20:32:20 |
| User entered '22 Sep 2020' | (b) (4), (b) (6) | 25 Sep 2020 16:04:11 |

US3742169

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:15:04

[End time \(00:00-23:59\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 20:32:20 |
| User entered empty. | (b) (4), (b) (6) | 25 Sep 2020 16:04:11 |

US3742169

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:15:04

[AE End Date and Time \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 25 Sep 2020 16:04:11 |



US3742169

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:15:04

[Severity](#)

| Audit                                              | User             | Time (GMT)           |
|----------------------------------------------------|------------------|----------------------|
| DataPoint Verified.                                | (b) (4), (b) (6) | 01 Oct 2020 20:32:20 |
| User entered 'Grade 2/Moderate (Grade 2/Moderate)' | (b) (4), (b) (6) | 25 Sep 2020 16:04:11 |

US3742169

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:15:04

[Is the adverse event serious?](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 01 Oct 2020 20:32:20 |
| User entered 'No (N)' | (b) (4), (b) (6) | 25 Sep 2020 16:04:11 |

US3742169

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:15:04

[Death](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 20:32:20 |
| User entered '0'    | (b) (4), (b) (6) | 25 Sep 2020 16:04:11 |

US3742169

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:15:04

[Life threatening](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 20:32:20 |
| User entered '0'    | (b) (4), (b) (6) | 25 Sep 2020 16:04:11 |

US3742169

**Folder:** Adverse Events

**Form:** Adverse Events (3)

**Generated On:** 26 Nov 2020 11:15:04

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 20:32:20 |
| User entered '0'    | (b) (4), (b) (6) | 25 Sep 2020 16:04:11 |

US3742169

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:15:04

[Hospital Admission Date \(dd MMM yyyy\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 20:32:20 |
| User entered empty. | (b) (4), (b) (6) | 25 Sep 2020 16:04:11 |

US3742169

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:15:04

Hospital Discharge Date (dd MMM yyyy)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 20:32:20 |
| User entered empty. | (b) (4), (b) (6) | 25 Sep 2020 16:04:11 |

US3742169

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:15:04

[Admitted to ICU?](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 20:32:20 |
| User entered empty. | (b) (4), (b) (6) | 25 Sep 2020 16:04:11 |



US3742169

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:15:04

[Number of Days in ICU](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 20:32:20 |
| User entered empty. | (b) (4), (b) (6) | 25 Sep 2020 16:04:11 |

US3742169

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:15:04

[Persistent or significant disability or incapacity](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 20:32:20 |
| User entered '0'    | (b) (4), (b) (6) | 25 Sep 2020 16:04:11 |

US3742169

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:15:04

[Congenital anomaly or birth defect](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 20:32:20 |
| User entered '0'    | (b) (4), (b) (6) | 25 Sep 2020 16:04:11 |

US3742169

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:15:04

[Other medically important event](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 20:32:20 |
| User entered '0'    | (b) (4), (b) (6) | 25 Sep 2020 16:04:11 |

US3742169

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:15:04

[Relationship to investigational product](#)

| Audit                                    | User             | Time (GMT)           |
|------------------------------------------|------------------|----------------------|
| DataPoint Verified.                      | (b) (4), (b) (6) | 01 Oct 2020 20:32:20 |
| User entered 'Not Related (NOT RELATED)' | (b) (4), (b) (6) | 25 Sep 2020 16:04:11 |

US3742169

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:15:04

[Relationship to Study Procedure](#)

| Audit                                    | User             | Time (GMT)           |
|------------------------------------------|------------------|----------------------|
| DataPoint Verified.                      | (b) (4), (b) (6) | 01 Oct 2020 20:32:20 |
| User entered 'Not Related (NOT RELATED)' | (b) (4), (b) (6) | 25 Sep 2020 16:04:11 |

US3742169

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:15:04

[Action taken with investigational product](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 01 Oct 2020 20:32:20 |
| User entered 'None (NONE)' | (b) (4), (b) (6) | 25 Sep 2020 16:04:11 |

US3742169

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:15:04

[None](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 20:32:20 |
| User entered '1'    | (b) (4), (b) (6) | 25 Sep 2020 16:04:11 |



US3742169

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:15:04

[Concomitant Medication](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 20:32:20 |
| User entered '0'    | (b) (4), (b) (6) | 25 Sep 2020 16:04:11 |

US3742169

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:15:04

[Concomitant Procedure](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 20:32:20 |
| User entered '0'    | (b) (4), (b) (6) | 25 Sep 2020 16:04:11 |

**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 26 Nov 2020 11:15:04**

[Outcome](#)

| Audit                                                  | User             | Time (GMT)           |
|--------------------------------------------------------|------------------|----------------------|
| DataPoint Verified.                                    | (b) (4), (b) (6) | 01 Oct 2020 20:32:20 |
| User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' | (b) (4), (b) (6) | 25 Sep 2020 16:04:11 |

US3742169

**Folder:** Adverse Events

**Form:** Adverse Events (3)

**Generated On:** 26 Nov 2020 11:15:04

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 20:32:20 |
| User entered empty. | (b) (4), (b) (6) | 25 Sep 2020 16:04:11 |

**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 26 Nov 2020 11:15:04**

[Narrative](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 20:32:20 |
| User entered empty. | (b) (4), (b) (6) | 25 Sep 2020 16:04:11 |

US3742169

**Folder:** Adverse Events

**Form:** Adverse Events (3)

**Generated On:** 26 Nov 2020 11:15:04

Serious Adverse Event Derived (CSA Programming Field Only)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '0' | System | 25 Sep 2020 16:04:11 |

US3742169

**Folder:** Adverse Events

**Form:** Adverse Events (3)

**Generated On:** 26 Nov 2020 11:15:04

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '0' | System | 25 Sep 2020 16:04:11 |

US3742169

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:15:04

[Adverse event](#)

| Audit                                                                                                                                                                                       | User                            | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------|----------------------|
| DataPoint Verified.                                                                                                                                                                         | (b) (4), (b) (6)                | 01 Oct 2020 20:32:20 |
| User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal signs and symptoms, HLT: Nausea and vomiting symptoms, PT: Vomiting, LLT: Vomiting - version MedDRA\\23.0. | Coder Import (b) (4)<br>(b) (4) | 25 Sep 2020 16:54:05 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.                                                                                                | Coder Import (b) (4)<br>(b) (4) | 25 Sep 2020 16:54:05 |
| Data point term sent to Coder                                                                                                                                                               | System                          | 25 Sep 2020 16:05:27 |
| User entered 'VOMITING'                                                                                                                                                                     | (b) (4), (b) (6)                | 25 Sep 2020 16:05:07 |



US3742169

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:15:04

[Was this a medically-attended AE?](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 01 Oct 2020 20:32:20 |
| User entered 'No (N)' | (b) (4), (b) (6) | 25 Sep 2020 16:05:07 |

US3742169

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:15:04

[Was this a Solicited Adverse Reaction?](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 01 Oct 2020 20:32:20 |
| User entered 'No (N)' | (b) (4), (b) (6) | 25 Sep 2020 16:05:07 |

US3742169

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:15:04

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 01 Oct 2020 20:32:20 |
| User entered 'No (N)' | (b) (4), (b) (6) | 25 Sep 2020 16:05:07 |

US3742169

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:15:04

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 01 Oct 2020 20:32:20 |
| User entered '19 Sep 2020' | (b) (4), (b) (6) | 25 Sep 2020 16:05:07 |

US3742169

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:15:04

[Start time \(00:00-23:59\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 20:32:20 |
| User entered empty. | (b) (4), (b) (6) | 25 Sep 2020 16:05:07 |

US3742169

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:15:04

[AE start date and time \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 25 Sep 2020 16:05:07 |

US3742169

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:15:04

[Ongoing?](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 01 Oct 2020 20:32:20 |
| User entered 'No (N)' | (b) (4), (b) (6) | 25 Sep 2020 16:05:07 |

US3742169

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:15:04

If not Ongoing, end date (dd MMM yyyy)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 01 Oct 2020 20:32:20 |
| User entered '20 Sep 2020' | (b) (4), (b) (6) | 25 Sep 2020 16:05:07 |



US3742169

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:15:04

End time (00:00-23:59)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 20:32:20 |
| User entered empty. | (b) (4), (b) (6) | 25 Sep 2020 16:05:07 |

US3742169

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:15:04

[AE End Date and Time \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 25 Sep 2020 16:05:07 |

US3742169

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:15:04

[Severity](#)

| Audit                                      | User             | Time (GMT)           |
|--------------------------------------------|------------------|----------------------|
| DataPoint Verified.                        | (b) (4), (b) (6) | 01 Oct 2020 20:32:20 |
| User entered 'Grade 1/Mild (Grade 1/Mild)' | (b) (4), (b) (6) | 25 Sep 2020 16:05:07 |

US3742169

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:15:04

[Is the adverse event serious?](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 01 Oct 2020 20:32:20 |
| User entered 'No (N)' | (b) (4), (b) (6) | 25 Sep 2020 16:05:07 |

US3742169

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:15:04

[Death](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 20:32:20 |
| User entered '0'    | (b) (4), (b) (6) | 25 Sep 2020 16:05:07 |

US3742169

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:15:04

[Life threatening](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 20:32:20 |
| User entered '0'    | (b) (4), (b) (6) | 25 Sep 2020 16:05:07 |

US3742169

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:15:04

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 20:32:20 |
| User entered '0'    | (b) (4), (b) (6) | 25 Sep 2020 16:05:07 |

US3742169

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:15:04

[Hospital Admission Date \(dd MMM yyyy\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 20:32:20 |
| User entered empty. | (b) (4), (b) (6) | 25 Sep 2020 16:05:07 |



US3742169

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:15:04

Hospital Discharge Date (dd MMM yyyy)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 20:32:20 |
| User entered empty. | (b) (4), (b) (6) | 25 Sep 2020 16:05:07 |

US3742169

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:15:04

[Admitted to ICU?](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 20:32:20 |
| User entered empty. | (b) (4), (b) (6) | 25 Sep 2020 16:05:07 |

US3742169

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:15:04

[Number of Days in ICU](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 20:32:20 |
| User entered empty. | (b) (4), (b) (6) | 25 Sep 2020 16:05:07 |

US3742169

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:15:04

[Persistent or significant disability or incapacity](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 20:32:20 |
| User entered '0'    | (b) (4), (b) (6) | 25 Sep 2020 16:05:07 |

US3742169

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:15:04

[Congenital anomaly or birth defect](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 20:32:20 |
| User entered '0'    | (b) (4), (b) (6) | 25 Sep 2020 16:05:07 |

US3742169

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:15:04

[Other medically important event](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 20:32:20 |
| User entered '0'    | (b) (4), (b) (6) | 25 Sep 2020 16:05:07 |

US3742169

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:15:04

[Relationship to investigational product](#)

| Audit                                    | User             | Time (GMT)           |
|------------------------------------------|------------------|----------------------|
| DataPoint Verified.                      | (b) (4), (b) (6) | 01 Oct 2020 20:32:20 |
| User entered 'Not Related (NOT RELATED)' | (b) (4), (b) (6) | 25 Sep 2020 16:05:07 |

US3742169

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:15:04

[Relationship to Study Procedure](#)

| Audit                                    | User             | Time (GMT)           |
|------------------------------------------|------------------|----------------------|
| DataPoint Verified.                      | (b) (4), (b) (6) | 01 Oct 2020 20:32:20 |
| User entered 'Not Related (NOT RELATED)' | (b) (4), (b) (6) | 25 Sep 2020 16:05:07 |



US3742169

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:15:04

[Action taken with investigational product](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 01 Oct 2020 20:32:20 |
| User entered 'None (NONE)' | (b) (4), (b) (6) | 25 Sep 2020 16:05:07 |

US3742169

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:15:04

[None](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 20:32:20 |
| User entered '1'    | (b) (4), (b) (6) | 25 Sep 2020 16:05:07 |

US3742169

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:15:04

[Concomitant Medication](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 20:32:20 |
| User entered '0'    | (b) (4), (b) (6) | 25 Sep 2020 16:05:07 |

US3742169

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:15:04

[Concomitant Procedure](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 20:32:20 |
| User entered '0'    | (b) (4), (b) (6) | 25 Sep 2020 16:05:07 |

**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 26 Nov 2020 11:15:04**

[Outcome](#)

| Audit                                                  | User             | Time (GMT)           |
|--------------------------------------------------------|------------------|----------------------|
| DataPoint Verified.                                    | (b) (4), (b) (6) | 01 Oct 2020 20:32:20 |
| User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' | (b) (4), (b) (6) | 25 Sep 2020 16:05:07 |

US3742169

**Folder:** Adverse Events

**Form:** Adverse Events (4)

**Generated On:** 26 Nov 2020 11:15:04

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 20:32:20 |
| User entered empty. | (b) (4), (b) (6) | 25 Sep 2020 16:05:07 |

US3742169

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:15:04

[Narrative](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 20:32:20 |
| User entered empty. | (b) (4), (b) (6) | 25 Sep 2020 16:05:07 |

US3742169

**Folder:** Adverse Events

**Form:** Adverse Events (4)

**Generated On:** 26 Nov 2020 11:15:04

Serious Adverse Event Derived (CSA Programming Field Only)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '0' | System | 25 Sep 2020 16:05:07 |



US3742169

**Folder:** Adverse Events

**Form:** Adverse Events (4)

**Generated On:** 26 Nov 2020 11:15:04

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '0' | System | 25 Sep 2020 16:05:07 |

US3742169

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:15:04

[Adverse event](#)

| Audit                                                                                                                                                                                                  | User                 | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|----------------------|
| DataPoint Verified.                                                                                                                                                                                    | (b) (4), (b) (6)     | 01 Oct 2020 20:32:20 |
| User coded data point as SOC: Psychiatric disorders, HLT: Sleep disorders and disturbances, HLT: Disturbances in initiating and maintaining sleep, PT: Insomnia, LLT: Insomnia - version MedDRA\\23.0. | Coder Import (b) (4) | 25 Sep 2020 16:54:08 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.                                                                                                           | (b) (4)              | 25 Sep 2020 16:54:08 |
| Data point term sent to Coder                                                                                                                                                                          | System               | 25 Sep 2020 16:06:27 |
| User entered 'INSOMNIA'                                                                                                                                                                                | (b) (4), (b) (6)     | 25 Sep 2020 16:06:12 |

US3742169

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:15:04

[Was this a medically-attended AE?](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 01 Oct 2020 20:32:20 |
| User entered 'No (N)' | (b) (4), (b) (6) | 25 Sep 2020 16:06:12 |

US3742169

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:15:04

[Was this a Solicited Adverse Reaction?](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 01 Oct 2020 20:32:20 |
| User entered 'No (N)' | (b) (4), (b) (6) | 25 Sep 2020 16:06:12 |

US3742169

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:15:04

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 01 Oct 2020 20:32:20 |
| User entered 'No (N)' | (b) (4), (b) (6) | 25 Sep 2020 16:06:12 |

US3742169

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:15:04

[Start date \(dd MMM yyyy\)](#)

| Audit                     | User             | Time (GMT)           |
|---------------------------|------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6) | 01 Oct 2020 20:32:20 |
| User entered '7 Sep 2020' | (b) (4), (b) (6) | 25 Sep 2020 16:06:12 |

US3742169

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:15:04

[Start time \(00:00-23:59\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 20:32:20 |
| User entered empty. | (b) (4), (b) (6) | 25 Sep 2020 16:06:12 |

US3742169

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:15:04

[AE start date and time \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 25 Sep 2020 16:06:12 |



US3742169

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:15:04

[Ongoing?](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 01 Oct 2020 20:32:20 |
| User entered 'No (N)' | (b) (4), (b) (6) | 25 Sep 2020 16:06:12 |

US3742169

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:15:04

If not Ongoing, end date (dd MMM yyyy)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 01 Oct 2020 20:32:20 |
| User entered '25 Sep 2020' | (b) (4), (b) (6) | 25 Sep 2020 16:06:12 |

US3742169

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:15:04

End time (00:00-23:59)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 20:32:20 |
| User entered empty. | (b) (4), (b) (6) | 25 Sep 2020 16:06:12 |

US3742169

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:15:04

[AE End Date and Time \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 25 Sep 2020 16:06:12 |

US3742169

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:15:04

[Severity](#)

| Audit                                              | User             | Time (GMT)           |
|----------------------------------------------------|------------------|----------------------|
| DataPoint Verified.                                | (b) (4), (b) (6) | 01 Oct 2020 20:32:20 |
| User entered 'Grade 2/Moderate (Grade 2/Moderate)' | (b) (4), (b) (6) | 25 Sep 2020 16:06:12 |

US3742169

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:15:04

[Is the adverse event serious?](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 01 Oct 2020 20:32:20 |
| User entered 'No (N)' | (b) (4), (b) (6) | 25 Sep 2020 16:06:12 |

US3742169

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:15:04

[Death](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 20:32:20 |
| User entered '0'    | (b) (4), (b) (6) | 25 Sep 2020 16:06:12 |

US3742169

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:15:04

[Life threatening](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 20:32:20 |
| User entered '0'    | (b) (4), (b) (6) | 25 Sep 2020 16:06:12 |



US3742169

**Folder:** Adverse Events

**Form:** Adverse Events (5)

**Generated On:** 26 Nov 2020 11:15:04

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 20:32:20 |
| User entered '0'    | (b) (4), (b) (6) | 25 Sep 2020 16:06:12 |

US3742169

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:15:04

[Hospital Admission Date \(dd MMM yyyy\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 20:32:20 |
| User entered empty. | (b) (4), (b) (6) | 25 Sep 2020 16:06:12 |

US3742169

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:15:04

Hospital Discharge Date (dd MMM yyyy)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 20:32:20 |
| User entered empty. | (b) (4), (b) (6) | 25 Sep 2020 16:06:12 |

US3742169

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:15:04

[Admitted to ICU?](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 20:32:20 |
| User entered empty. | (b) (4), (b) (6) | 25 Sep 2020 16:06:12 |

US3742169

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:15:04

[Number of Days in ICU](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 20:32:20 |
| User entered empty. | (b) (4), (b) (6) | 25 Sep 2020 16:06:12 |

US3742169

**Folder:** Adverse Events

**Form:** Adverse Events (5)

**Generated On:** 26 Nov 2020 11:15:04

[Persistent or significant disability or incapacity](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 20:32:20 |
| User entered '0'    | (b) (4), (b) (6) | 25 Sep 2020 16:06:12 |

US3742169

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:15:04

[Congenital anomaly or birth defect](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 20:32:20 |
| User entered '0'    | (b) (4), (b) (6) | 25 Sep 2020 16:06:12 |

US3742169

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:15:04

[Other medically important event](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 20:32:20 |
| User entered '0'    | (b) (4), (b) (6) | 25 Sep 2020 16:06:12 |



US3742169

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:15:04

[Relationship to investigational product](#)

| Audit                                    | User             | Time (GMT)           |
|------------------------------------------|------------------|----------------------|
| DataPoint Verified.                      | (b) (4), (b) (6) | 01 Oct 2020 20:32:20 |
| User entered 'Not Related (NOT RELATED)' | (b) (4), (b) (6) | 25 Sep 2020 16:06:12 |

US3742169

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:15:04

[Relationship to Study Procedure](#)

| Audit                                    | User             | Time (GMT)           |
|------------------------------------------|------------------|----------------------|
| DataPoint Verified.                      | (b) (4), (b) (6) | 01 Oct 2020 20:32:20 |
| User entered 'Not Related (NOT RELATED)' | (b) (4), (b) (6) | 25 Sep 2020 16:06:12 |

US3742169

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:15:04

[Action taken with investigational product](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 01 Oct 2020 20:32:20 |
| User entered 'None (NONE)' | (b) (4), (b) (6) | 25 Sep 2020 16:06:12 |

US3742169

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:15:04

[None](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 20:32:20 |
| User entered '1'    | (b) (4), (b) (6) | 25 Sep 2020 16:06:12 |

US3742169

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:15:04

[Concomitant Medication](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 20:32:20 |
| User entered '0'    | (b) (4), (b) (6) | 25 Sep 2020 16:06:12 |

US3742169

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:15:04

[Concomitant Procedure](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 20:32:20 |
| User entered '0'    | (b) (4), (b) (6) | 25 Sep 2020 16:06:12 |

**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 26 Nov 2020 11:15:04**

[Outcome](#)

| Audit                                                     | User             | Time (GMT)           |
|-----------------------------------------------------------|------------------|----------------------|
| DataPoint Verified.                                       | (b) (4), (b) (6) | 01 Oct 2020 20:32:20 |
| User entered 'Recovered/Resolved<br>(RECOVERED/RESOLVED)' | (b) (4), (b) (6) | 25 Sep 2020 16:06:12 |

US3742169

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:15:04

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 20:32:20 |
| User entered empty. | (b) (4), (b) (6) | 25 Sep 2020 16:06:12 |



US3742169

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:15:04

[Narrative](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 20:32:20 |
| User entered empty. | (b) (4), (b) (6) | 25 Sep 2020 16:06:12 |

US3742169

**Folder:** Adverse Events

**Form:** Adverse Events (5)

**Generated On:** 26 Nov 2020 11:15:04

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '0' | System | 25 Sep 2020 16:06:12 |

US3742169

**Folder:** Adverse Events

**Form:** Adverse Events (5)

**Generated On:** 26 Nov 2020 11:15:04

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '0' | System | 25 Sep 2020 16:06:12 |

US3742169

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:15:04

[Adverse event](#)

| Audit                                                                                                                                                                                                                                          | User                               | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------|----------------------|
| DataPoint Verified.                                                                                                                                                                                                                            | (b) (4), (b) (6)                   | 28 Oct 2020 15:58:47 |
| User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Constipation, LLT: Constipation - version MedDRA\\23.0. | Coder Import (b) (4)<br>(b) (4)    | 27 Oct 2020 16:32:42 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.                                                                                                                                                   | Coder Import (b) (4)<br>(b) (4)    | 27 Oct 2020 16:32:42 |
| Data point term sent to Coder                                                                                                                                                                                                                  | System                             | 27 Oct 2020 16:31:19 |
| User entered 'CONSTIPATION'                                                                                                                                                                                                                    | Sherry McCammon (b) (4)<br>(b) (4) | 27 Oct 2020 16:30:45 |

US3742169

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:15:04

[Was this a medically-attended AE?](#)

| Audit                                                                                  | User                    | Time (GMT)           |
|----------------------------------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                                                    | (b) (4), (b) (6)        | 28 Oct 2020 15:58:47 |
| User closed query 'Data is required. Please complete.' (Site from System).             | System                  | 28 Oct 2020 13:47:29 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System                  | 28 Oct 2020 13:47:29 |
| User entered 'No (N)' reason for change: Data Entry Error                              | Kaitlin Mason (b) (4)   | 28 Oct 2020 13:47:29 |
| User opened query 'Data is required. Please complete.' (Site from System).             | System                  | 27 Oct 2020 16:30:45 |
| User entered empty.                                                                    | Sherry McCammon (b) (4) | 27 Oct 2020 16:30:45 |

US3742169

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:15:04

[Was this a Solicited Adverse Reaction?](#)

| Audit                                                                                  | User                    | Time (GMT)           |
|----------------------------------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                                                    | (b) (4), (b) (6)        | 28 Oct 2020 15:58:47 |
| User closed query 'Data is required. Please complete.' (Site from System).             | System                  | 28 Oct 2020 13:47:29 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System                  | 28 Oct 2020 13:47:29 |
| User entered 'No (N)' reason for change: Data Entry Error                              | Kaitlin Mason (b) (4)   | 28 Oct 2020 13:47:29 |
| User opened query 'Data is required. Please complete.' (Site from System).             | System                  | 27 Oct 2020 16:30:45 |
| User entered empty.                                                                    | Sherry McCammon (b) (4) | 27 Oct 2020 16:30:45 |

US3742169

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:15:04

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit                                                                                  | User                    | Time (GMT)           |
|----------------------------------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                                                    | (b) (4), (b) (6)        | 28 Oct 2020 15:58:47 |
| User closed query 'Data is required. Please complete.' (Site from System).             | System                  | 28 Oct 2020 13:47:29 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System                  | 28 Oct 2020 13:47:29 |
| User entered 'No (N)' reason for change: Data Entry Error                              | Kaitlin Mason (b) (4)   | 28 Oct 2020 13:47:29 |
| User opened query 'Data is required. Please complete.' (Site from System).             | (b) (4)                 |                      |
| User entered empty.                                                                    | System                  | 27 Oct 2020 16:30:45 |
|                                                                                        | Sherry McCammon (b) (4) | 27 Oct 2020 16:30:45 |
|                                                                                        | (b) (4)                 |                      |

US3742169

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:15:04

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                    | Time (GMT)           |
|----------------------------|-------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)        | 28 Oct 2020 15:58:47 |
| User entered '22 Oct 2020' | Sherry McCammon (b) (4) | 27 Oct 2020 16:30:45 |
|                            | (b) (4)                 |                      |



US3742169

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:15:04

Start time (00:00-23:59)

| Audit               | User                    | Time (GMT)           |
|---------------------|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)        | 28 Oct 2020 15:58:47 |
| User entered empty. | Sherry McCammon (b) (4) | 27 Oct 2020 16:30:45 |
|                     | (b) (4)                 |                      |

US3742169

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:15:04

[AE start date and time \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 27 Oct 2020 16:30:45 |

US3742169

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:15:04

[Ongoing?](#)

| Audit                  | User                    | Time (GMT)           |
|------------------------|-------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)        | 28 Oct 2020 15:58:47 |
| User entered 'Yes (Y)' | Sherry McCammon (b) (4) | 27 Oct 2020 16:30:45 |
|                        | (b) (4)                 |                      |

US3742169

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:15:04

If not Ongoing, end date (dd MMM yyyy)

| Audit               | User                    | Time (GMT)           |
|---------------------|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)        | 28 Oct 2020 15:58:47 |
| User entered empty. | Sherry McCammon (b) (4) | 27 Oct 2020 16:30:45 |
|                     | (b) (4)                 |                      |

US3742169

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:15:04

End time (00:00-23:59)

| Audit               | User                    | Time (GMT)           |
|---------------------|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)        | 28 Oct 2020 15:58:47 |
| User entered empty. | Sherry McCammon (b) (4) | 27 Oct 2020 16:30:45 |
|                     | (b) (4)                 |                      |

US3742169

**Folder:** Adverse Events

**Form:** Adverse Events (6)

**Generated On:** 26 Nov 2020 11:15:04

[AE End Date and Time \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 27 Oct 2020 16:30:45 |

US3742169

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:15:04

[Severity](#)

| Audit                                              | User                    | Time (GMT)           |
|----------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                | (b) (4), (b) (6)        | 28 Oct 2020 15:58:47 |
| User entered 'Grade 2/Moderate (Grade 2/Moderate)' | Sherry McCammon (b) (4) | 27 Oct 2020 16:30:45 |
|                                                    | (b) (4)                 |                      |

US3742169

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:15:04

[Is the adverse event serious?](#)

| Audit                                                                                  | User                    | Time (GMT)           |
|----------------------------------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                                                    | (b) (4), (b) (6)        | 28 Oct 2020 15:58:47 |
| User closed query 'Data is required. Please complete.' (Site from System).             | System                  | 28 Oct 2020 13:47:29 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System                  | 28 Oct 2020 13:47:29 |
| User entered 'No (N)' reason for change: Data Entry Error                              | Kaitlin Mason (b) (4)   | 28 Oct 2020 13:47:29 |
| User opened query 'Data is required. Please complete.' (Site from System).             | System                  | 27 Oct 2020 16:30:45 |
| User entered empty.                                                                    | Sherry McCammon (b) (4) | 27 Oct 2020 16:30:45 |



US3742169

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:15:04

[Death](#)

| Audit               | User                    | Time (GMT)           |
|---------------------|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)        | 28 Oct 2020 15:58:47 |
| User entered '0'    | Sherry McCammon (b) (4) | 27 Oct 2020 16:30:45 |
|                     | (b) (4)                 |                      |

US3742169

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:15:04

[Life threatening](#)

| Audit               | User                    | Time (GMT)           |
|---------------------|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)        | 28 Oct 2020 15:58:47 |
| User entered '0'    | Sherry McCammon (b) (4) | 27 Oct 2020 16:30:45 |
|                     | (b) (4)                 |                      |

US3742169

**Folder:** Adverse Events

**Form:** Adverse Events (6)

**Generated On:** 26 Nov 2020 11:15:04

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit               | User                    | Time (GMT)           |
|---------------------|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)        | 28 Oct 2020 15:58:47 |
| User entered '0'    | Sherry McCammon (b) (4) | 27 Oct 2020 16:30:45 |
|                     | (b) (4)                 |                      |

US3742169

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:15:04

Hospital Admission Date (*dd MMM yyyy*)

| Audit               | User                    | Time (GMT)           |
|---------------------|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)        | 28 Oct 2020 15:58:47 |
| User entered empty. | Sherry McCammon (b) (4) | 27 Oct 2020 16:30:45 |
|                     | (b) (4)                 |                      |

US3742169

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:15:04

Hospital Discharge Date (dd MMM yyyy)

| Audit               | User                    | Time (GMT)           |
|---------------------|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)        | 28 Oct 2020 15:58:47 |
| User entered empty. | Sherry McCammon (b) (4) | 27 Oct 2020 16:30:45 |
|                     | (b) (4)                 |                      |

US3742169

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:15:04

[Admitted to ICU?](#)

| Audit               | User                    | Time (GMT)           |
|---------------------|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)        | 28 Oct 2020 15:58:47 |
| User entered empty. | Sherry McCammon (b) (4) | 27 Oct 2020 16:30:45 |
|                     | (b) (4)                 |                      |

US3742169

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:15:04

[Number of Days in ICU](#)

| Audit               | User                    | Time (GMT)           |
|---------------------|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)        | 28 Oct 2020 15:58:47 |
| User entered empty. | Sherry McCammon (b) (4) | 27 Oct 2020 16:30:45 |
|                     | (b) (4)                 |                      |

US3742169

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:15:04

[Persistent or significant disability or incapacity](#)

| Audit               | User                    | Time (GMT)           |
|---------------------|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)        | 28 Oct 2020 15:58:47 |
| User entered '0'    | Sherry McCammon (b) (4) | 27 Oct 2020 16:30:45 |
|                     | (b) (4)                 |                      |



US3742169

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:15:04

[Congenital anomaly or birth defect](#)

| Audit               | User                    | Time (GMT)           |
|---------------------|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)        | 28 Oct 2020 15:58:47 |
| User entered '0'    | Sherry McCammon (b) (4) | 27 Oct 2020 16:30:45 |
|                     | (b) (4)                 |                      |

US3742169

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:15:04

[Other medically important event](#)

| Audit               | User                    | Time (GMT)           |
|---------------------|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)        | 28 Oct 2020 15:58:47 |
| User entered '0'    | Sherry McCammon (b) (4) | 27 Oct 2020 16:30:45 |
|                     | (b) (4)                 |                      |

US3742169

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:15:04

[Relationship to investigational product](#)

| Audit                                                                                  | User                    | Time (GMT)           |
|----------------------------------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                                                    | (b) (4), (b) (6)        | 28 Oct 2020 15:58:47 |
| User closed query 'Data is required. Please complete.' (Site from System).             | System                  | 28 Oct 2020 13:47:29 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System                  | 28 Oct 2020 13:47:29 |
| User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error           | Kaitlin Mason (b) (4)   | 28 Oct 2020 13:47:29 |
| User opened query 'Data is required. Please complete.' (Site from System).             | (b) (4)                 |                      |
| User entered empty.                                                                    | System                  | 27 Oct 2020 16:30:45 |
|                                                                                        | Sherry McCammon (b) (4) | 27 Oct 2020 16:30:45 |
|                                                                                        | (b) (4)                 |                      |

US3742169

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:15:04

[Relationship to Study Procedure](#)

| Audit                                                                                  | User                    | Time (GMT)           |
|----------------------------------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                                                    | (b) (4), (b) (6)        | 28 Oct 2020 15:58:47 |
| User closed query 'Data is required. Please complete.' (Site from System).             | System                  | 28 Oct 2020 13:47:29 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System                  | 28 Oct 2020 13:47:29 |
| User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error           | Kaitlin Mason (b) (4)   | 28 Oct 2020 13:47:29 |
| User opened query 'Data is required. Please complete.' (Site from System).             | (b) (4)                 |                      |
| User entered empty.                                                                    | System                  | 27 Oct 2020 16:30:45 |
|                                                                                        | Sherry McCammon (b) (4) | 27 Oct 2020 16:30:45 |
|                                                                                        | (b) (4)                 |                      |

US3742169

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:15:04

[Action taken with investigational product](#)

| Audit                                                                                  | User                    | Time (GMT)           |
|----------------------------------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                                                    | (b) (4), (b) (6)        | 28 Oct 2020 15:58:47 |
| User closed query 'Data is required. Please complete.' (Site from System).             | System                  | 28 Oct 2020 13:47:29 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System                  | 28 Oct 2020 13:47:29 |
| User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error     | Kaitlin Mason (b) (4)   | 28 Oct 2020 13:47:29 |
| User opened query 'Data is required. Please complete.' (Site from System).             | (b) (4)                 | 27 Oct 2020 16:30:45 |
| User entered empty.                                                                    | Sherry McCammon (b) (4) | 27 Oct 2020 16:30:45 |
|                                                                                        | (b) (4)                 |                      |

US3742169

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:15:04

[None](#)

| Audit                                                                                                                              | User                    | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                                                                                                | (b) (4), (b) (6)        | 28 Oct 2020 15:58:47 |
| User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System). | System                  | 28 Oct 2020 13:47:29 |
| User entered '1' reason for change: Data Entry Error                                                                               | Kaitlin Mason (b) (4)   | 28 Oct 2020 13:47:29 |
| User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System). | (b) (4)                 | 27 Oct 2020 16:30:45 |
| User entered '0'                                                                                                                   | System                  | 27 Oct 2020 16:30:45 |
|                                                                                                                                    | Sherry McCammon (b) (4) | 27 Oct 2020 16:30:45 |
|                                                                                                                                    | (b) (4)                 |                      |

US3742169

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:15:04

[Concomitant Medication](#)

| Audit               | User                    | Time (GMT)           |
|---------------------|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)        | 28 Oct 2020 15:58:47 |
| User entered '0'    | Sherry McCammon (b) (4) | 27 Oct 2020 16:30:45 |
|                     | (b) (4)                 |                      |

US3742169

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:15:04

[Concomitant Procedure](#)

| Audit               | User                    | Time (GMT)           |
|---------------------|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)        | 28 Oct 2020 15:58:47 |
| User entered '0'    | Sherry McCammon (b) (4) | 27 Oct 2020 16:30:45 |
|                     | (b) (4)                 |                      |



US3742169

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:15:04

[Outcome](#)

| Audit                                                                                          | User                               | Time (GMT)           |
|------------------------------------------------------------------------------------------------|------------------------------------|----------------------|
| DataPoint Verified.                                                                            | (b) (4), (b) (6)                   | 28 Oct 2020 15:58:47 |
| User closed query 'Data is required. Please complete.' (Site from System).                     | System                             | 28 Oct 2020 13:47:29 |
| Query 'Data is required. Please complete.' answered by data change (Site from System).         | System                             | 28 Oct 2020 13:47:29 |
| User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change: Data Entry Error | Kaitlin Mason (b) (4)<br>(b) (4)   | 28 Oct 2020 13:47:29 |
| User opened query 'Data is required. Please complete.' (Site from System).                     | System                             | 27 Oct 2020 16:30:45 |
| User entered empty.                                                                            | Sherry McCammon (b) (4)<br>(b) (4) | 27 Oct 2020 16:30:45 |

US3742169

**Folder:** Adverse Events

**Form:** Adverse Events (6)

**Generated On:** 26 Nov 2020 11:15:04

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

| Audit               | User                    | Time (GMT)           |
|---------------------|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)        | 28 Oct 2020 15:58:47 |
| User entered empty. | Sherry McCammon (b) (4) | 27 Oct 2020 16:30:45 |
|                     | (b) (4)                 |                      |

US3742169

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:15:04

[Narrative](#)

| Audit               | User                    | Time (GMT)           |
|---------------------|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)        | 28 Oct 2020 15:58:47 |
| User entered empty. | Sherry McCammon (b) (4) | 27 Oct 2020 16:30:45 |
|                     | (b) (4)                 |                      |

US3742169

**Folder:** Adverse Events

**Form:** Adverse Events (6)

**Generated On:** 26 Nov 2020 11:15:04

Serious Adverse Event Derived (CSA Programming Field Only)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '0' | System | 28 Oct 2020 13:47:29 |

US3742169

**Folder:** Adverse Events

**Form:** Adverse Events (6)

**Generated On:** 26 Nov 2020 11:15:04

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '0' | System | 28 Oct 2020 13:47:29 |

US3742169

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:15:04

[Adverse event](#)

| Audit                                                                                                                                                                                         | User                    | Time (GMT)           |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|----------------------|
| User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Viral infections NEC, PT: Viral infection, LLT: Viral infection NOS - version MedDRA\\23.0. | Coder Import (b) (4)    | 19 Nov 2020 20:42:02 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.                                                                                                  | Coder Import (b) (4)    | 19 Nov 2020 20:42:02 |
| Data point term sent to Coder                                                                                                                                                                 | System                  | 19 Nov 2020 20:26:29 |
| Coding entries removed.                                                                                                                                                                       | Sherry McCammon (b) (4) | 19 Nov 2020 20:26:27 |
| User entered 'VIRAL ILLNESS UNSPECIFIED' reason for change: Data Entry Error                                                                                                                  | Sherry McCammon (b) (4) | 19 Nov 2020 20:26:27 |
| User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Viral infections NEC, PT: Viral infection, LLT: Viral syndrome - version MedDRA\\23.0.      | Coder Import (b) (4)    | 19 Nov 2020 18:34:01 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.                                                                                                  | Coder Import (b) (4)    | 19 Nov 2020 18:34:01 |
| Data point term sent to Coder                                                                                                                                                                 | System                  | 19 Nov 2020 18:18:40 |
| User entered 'Viral Syndrome'                                                                                                                                                                 | (b) (4), (b) (6)        | 19 Nov 2020 18:18:16 |

US3742169

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:15:04

[Was this a medically-attended AE?](#)

| Audit                                                                                  | User                                 | Time (GMT)           |
|----------------------------------------------------------------------------------------|--------------------------------------|----------------------|
| User closed query 'Data is required. Please complete.' (Site from System).             | System                               | 19 Nov 2020 20:22:52 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System                               | 19 Nov 2020 20:22:52 |
| User entered 'Yes (Y)' reason for change: Data Entry Error                             | Sherry McCammon (b) (4)<br>(b) (4)   | 19 Nov 2020 20:22:52 |
| User opened query 'Data is required. Please complete.' (Site from System).             | System                               | 19 Nov 2020 18:18:16 |
| User entered empty.                                                                    | (b) (4), (b) (6)<br>(b) (4), (b) (6) | 19 Nov 2020 18:18:16 |

US3742169

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:15:04

[Was this a Solicited Adverse Reaction?](#)

| Audit                                                                                  | User                                 | Time (GMT)           |
|----------------------------------------------------------------------------------------|--------------------------------------|----------------------|
| User closed query 'Data is required. Please complete.' (Site from System).             | System                               | 19 Nov 2020 20:22:52 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System                               | 19 Nov 2020 20:22:52 |
| User entered 'No (N)' reason for change: Data Entry Error                              | Sherry McCammon (b) (4)<br>(b) (4)   | 19 Nov 2020 20:22:52 |
| User opened query 'Data is required. Please complete.' (Site from System).             | System                               | 19 Nov 2020 18:18:16 |
| User entered empty.                                                                    | (b) (4), (b) (6)<br>(b) (4), (b) (6) | 19 Nov 2020 18:18:16 |



US3742169

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:15:04

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit                                                                                  | User                                 | Time (GMT)           |
|----------------------------------------------------------------------------------------|--------------------------------------|----------------------|
| User closed query 'Data is required. Please complete.' (Site from System).             | System                               | 19 Nov 2020 20:22:52 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System                               | 19 Nov 2020 20:22:52 |
| User entered 'No (N)' reason for change: Data Entry Error                              | Sherry McCammon (b) (4)<br>(b) (4)   | 19 Nov 2020 20:22:52 |
| User opened query 'Data is required. Please complete.' (Site from System).             | System                               | 19 Nov 2020 18:18:16 |
| User entered empty.                                                                    | (b) (4), (b) (6)<br>(b) (4), (b) (6) | 19 Nov 2020 18:18:16 |

US3742169

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:15:04

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| User entered '31 Oct 2020' | (b) (4), (b) (6) | 19 Nov 2020 18:18:16 |
|                            |                  |                      |

US3742169

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:15:04

[Start time \(00:00-23:59\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 19 Nov 2020 18:18:16 |
|                     |                  |                      |

US3742169

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:15:04

[AE start date and time \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 19 Nov 2020 18:18:16 |

US3742169

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:15:04

[Ongoing?](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| User entered 'No (N)' | (b) (4), (b) (6) | 19 Nov 2020 18:18:16 |
|                       |                  |                      |

US3742169

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:15:04

If not Ongoing, end date (dd MMM yyyy)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| User entered '14 Nov 2020' | (b) (4), (b) (6) | 19 Nov 2020 18:18:16 |
|                            |                  |                      |

US3742169

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:15:04

End time (00:00-23:59)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 19 Nov 2020 18:18:16 |
|                     |                  |                      |

US3742169

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:15:04

[AE End Date and Time \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 19 Nov 2020 18:18:16 |



US3742169

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:15:04

[Severity](#)

| Audit                                              | User             | Time (GMT)           |
|----------------------------------------------------|------------------|----------------------|
| User entered 'Grade 2/Moderate (Grade 2/Moderate)' | (b) (4), (b) (6) | 19 Nov 2020 18:18:16 |

US3742169

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:15:04

[Is the adverse event serious?](#)

| Audit                                                                                  | User                                 | Time (GMT)           |
|----------------------------------------------------------------------------------------|--------------------------------------|----------------------|
| User closed query 'Data is required. Please complete.' (Site from System).             | System                               | 19 Nov 2020 20:22:52 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System                               | 19 Nov 2020 20:22:52 |
| User entered 'No (N)' reason for change: Data Entry Error                              | Sherry McCammon (b) (4)<br>(b) (4)   | 19 Nov 2020 20:22:52 |
| User opened query 'Data is required. Please complete.' (Site from System).             | System                               | 19 Nov 2020 18:18:16 |
| User entered empty.                                                                    | (b) (4), (b) (6)<br>(b) (4), (b) (6) | 19 Nov 2020 18:18:16 |

US3742169

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:15:04

[Death](#)

| Audit            | User             | Time (GMT)           |
|------------------|------------------|----------------------|
| User entered '0' | (b) (4), (b) (6) | 19 Nov 2020 18:18:16 |
|                  |                  |                      |

US3742169

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:15:04

[Life threatening](#)

| Audit            | User             | Time (GMT)           |
|------------------|------------------|----------------------|
| User entered '0' | (b) (4), (b) (6) | 19 Nov 2020 18:18:16 |
|                  |                  |                      |

US3742169

**Folder:** Adverse Events

**Form:** Adverse Events (7)

**Generated On:** 26 Nov 2020 11:15:04

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit            | User             | Time (GMT)           |
|------------------|------------------|----------------------|
| User entered '0' | (b) (4), (b) (6) | 19 Nov 2020 18:18:16 |
|                  |                  |                      |

US3742169

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:15:04

[Hospital Admission Date \(dd MMM yyyy\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 19 Nov 2020 18:18:16 |
|                     |                  |                      |

US3742169

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:15:04

[Hospital Discharge Date \(dd MMM yyyy\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 19 Nov 2020 18:18:16 |
|                     |                  |                      |

US3742169

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:15:04

[Admitted to ICU?](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 19 Nov 2020 18:18:16 |
|                     |                  |                      |



US3742169

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:15:04

[Number of Days in ICU](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 19 Nov 2020 18:18:16 |
|                     |                  |                      |

US3742169

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:15:04

[Persistent or significant disability or incapacity](#)

| Audit            | User             | Time (GMT)           |
|------------------|------------------|----------------------|
| User entered '0' | (b) (4), (b) (6) | 19 Nov 2020 18:18:16 |
|                  |                  |                      |

US3742169

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:15:04

[Congenital anomaly or birth defect](#)

| Audit            | User             | Time (GMT)           |
|------------------|------------------|----------------------|
| User entered '0' | (b) (4), (b) (6) | 19 Nov 2020 18:18:16 |
|                  |                  |                      |

US3742169

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:15:04

[Other medically important event](#)

| Audit            | User             | Time (GMT)           |
|------------------|------------------|----------------------|
| User entered '0' | (b) (4), (b) (6) | 19 Nov 2020 18:18:16 |
|                  |                  |                      |

US3742169

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:15:04

[Relationship to investigational product](#)

| Audit                                                                                  | User                                 | Time (GMT)           |
|----------------------------------------------------------------------------------------|--------------------------------------|----------------------|
| User closed query 'Data is required. Please complete.' (Site from System).             | System                               | 19 Nov 2020 20:22:52 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System                               | 19 Nov 2020 20:22:52 |
| User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error           | Sherry McCammon (b) (4)<br>(b) (4)   | 19 Nov 2020 20:22:52 |
| User opened query 'Data is required. Please complete.' (Site from System).             | System                               | 19 Nov 2020 18:18:16 |
| User entered empty.                                                                    | (b) (4), (b) (6)<br>(b) (4), (b) (6) | 19 Nov 2020 18:18:16 |

US3742169

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:15:04

[Relationship to Study Procedure](#)

| Audit                                                                                  | User                                 | Time (GMT)           |
|----------------------------------------------------------------------------------------|--------------------------------------|----------------------|
| User closed query 'Data is required. Please complete.' (Site from System).             | System                               | 19 Nov 2020 20:22:52 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System                               | 19 Nov 2020 20:22:52 |
| User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error           | Sherry McCammon (b) (4)<br>(b) (4)   | 19 Nov 2020 20:22:52 |
| User opened query 'Data is required. Please complete.' (Site from System).             | System                               | 19 Nov 2020 18:18:16 |
| User entered empty.                                                                    | (b) (4), (b) (6)<br>(b) (4), (b) (6) | 19 Nov 2020 18:18:16 |

US3742169

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:15:04

[Action taken with investigational product](#)

| Audit                                                                                  | User                                 | Time (GMT)           |
|----------------------------------------------------------------------------------------|--------------------------------------|----------------------|
| User closed query 'Data is required. Please complete.' (Site from System).             | System                               | 19 Nov 2020 20:22:52 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System                               | 19 Nov 2020 20:22:52 |
| User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error     | Sherry McCammon (b) (4)<br>(b) (4)   | 19 Nov 2020 20:22:52 |
| User opened query 'Data is required. Please complete.' (Site from System).             | System                               | 19 Nov 2020 18:18:16 |
| User entered empty.                                                                    | (b) (4), (b) (6)<br>(b) (4), (b) (6) | 19 Nov 2020 18:18:16 |

US3742169

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:15:04

[None](#)

| Audit                                                                                                                              | User             | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System). | System           | 19 Nov 2020 20:23:08 |
| User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System). | System           | 19 Nov 2020 18:18:16 |
| User entered '0'                                                                                                                   | (b) (4), (b) (6) | 19 Nov 2020 18:18:16 |
|                                                                                                                                    |                  |                      |



US3742169

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:15:04

[Concomitant Medication](#)

| Audit                                                | User                        | Time (GMT)           |
|------------------------------------------------------|-----------------------------|----------------------|
| User entered '1' reason for change: Data Entry Error | Sherry McCammon (b) (4)     | 19 Nov 2020 20:23:08 |
| User entered '0'                                     | (b) (4)<br>(b) (4), (b) (6) | 19 Nov 2020 18:18:16 |

US3742169

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:15:04

[Concomitant Procedure](#)

| Audit            | User             | Time (GMT)           |
|------------------|------------------|----------------------|
| User entered '0' | (b) (4), (b) (6) | 19 Nov 2020 18:18:16 |
|                  |                  |                      |

US3742169

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:15:04

[Outcome](#)

| Audit                                                  | User             | Time (GMT)           |
|--------------------------------------------------------|------------------|----------------------|
| User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' | (b) (4), (b) (6) | 19 Nov 2020 18:18:16 |

US3742169

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:15:04

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 19 Nov 2020 18:18:16 |
|                     |                  |                      |

US3742169

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:15:04

[Narrative](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 19 Nov 2020 18:18:16 |
|                     |                  |                      |

US3742169

**Folder:** Adverse Events

**Form:** Adverse Events (7)

**Generated On:** 26 Nov 2020 11:15:04

Serious Adverse Event Derived (CSA Programming Field Only)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '0' | System | 19 Nov 2020 20:22:52 |

**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 26 Nov 2020 11:15:04**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 19 Nov 2020 20:22:52 |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination Summary**

**Generated On: 26 Nov 2020 11:15:04**

[Were any prior/concomitant medications and/or vaccinations taken?](#)

| Audit                  | User                             | Time (GMT)           |
|------------------------|----------------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)                 | 01 Oct 2020 20:34:19 |
| User entered 'Yes (Y)' | Kaitlin Mason (b) (4)<br>(b) (4) | 11 Sep 2020 22:44:30 |



US3742169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:15:04

[Name of Medication](#)

| Audit                                                                                                                                                                                                                                                                  | User                             | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------|----------------------|
| DataPoint Verified.                                                                                                                                                                                                                                                    | (b) (4), (b) (6)                 | 01 Oct 2020 20:35:28 |
| User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: RABEPRAZOLE - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4)  | 11 Sep 2020 22:47:43 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.                                                                                                                                                              | Coder Import (b) (4)<br>(b) (4)  | 11 Sep 2020 22:47:43 |
| Data point term sent to Coder                                                                                                                                                                                                                                          | System                           | 11 Sep 2020 22:47:06 |
| User entered 'RABEPRAZOLE'                                                                                                                                                                                                                                             | Kaitlin Mason (b) (4)<br>(b) (4) | 11 Sep 2020 22:47:01 |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 11:15:04**

[Prophylaxis](#)

| Audit                 | User                             | Time (GMT)           |
|-----------------------|----------------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)                 | 01 Oct 2020 20:35:28 |
| User entered 'No (N)' | Kaitlin Mason (b) (4)<br>(b) (4) | 11 Sep 2020 22:47:01 |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 11:15:04**

[Indication](#)

| Audit                                          | User                             | Time (GMT)           |
|------------------------------------------------|----------------------------------|----------------------|
| DataPoint Verified.                            | (b) (4), (b) (6)                 | 01 Oct 2020 20:35:28 |
| User entered 'GASTROESOPHAGEAL REFLUX DISEASE' | Kaitlin Mason (b) (4)<br>(b) (4) | 11 Sep 2020 22:47:01 |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 11:15:04**

[Dose per administration](#)

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                 | 01 Oct 2020 20:35:28 |
| User entered '20'   | Kaitlin Mason (b) (4)<br>(b) (4) | 11 Sep 2020 22:47:01 |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 11:15:04**

[Dose unit](#)

| Audit                  | User                             | Time (GMT)           |
|------------------------|----------------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)                 | 01 Oct 2020 20:35:28 |
| User entered 'mg (mg)' | Kaitlin Mason (b) (4)<br>(b) (4) | 11 Sep 2020 22:47:01 |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 11:15:04**

If dose unit is Other, specify

| Audit               | User                  | Time (GMT)           |
|---------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)      | 01 Oct 2020 20:35:28 |
| User entered empty. | Kaitlin Mason (b) (4) | 11 Sep 2020 22:47:01 |
|                     | (b) (4)               |                      |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 11:15:04**

[Frequency](#)

| Audit                          | User                             | Time (GMT)           |
|--------------------------------|----------------------------------|----------------------|
| DataPoint Verified.            | (b) (4), (b) (6)                 | 01 Oct 2020 20:35:28 |
| User entered 'once daily (QD)' | Kaitlin Mason (b) (4)<br>(b) (4) | 11 Sep 2020 22:47:01 |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 11:15:04**

[If frequency is Other, specify](#)

| Audit               | User                  | Time (GMT)           |
|---------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)      | 01 Oct 2020 20:35:28 |
| User entered empty. | Kaitlin Mason (b) (4) | 11 Sep 2020 22:47:01 |
|                     | (b) (4)               |                      |



US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 11:15:04**

[Route of administration](#)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                 | 01 Oct 2020 20:35:28 |
| User entered 'Oral (ORAL)' | Kaitlin Mason (b) (4)<br>(b) (4) | 11 Sep 2020 22:47:01 |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 11:15:04**

If route of administration is Other, specify

| Audit               | User                  | Time (GMT)           |
|---------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)      | 01 Oct 2020 20:35:28 |
| User entered empty. | Kaitlin Mason (b) (4) | 11 Sep 2020 22:47:01 |
|                     | (b) (4)               |                      |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 11:15:04**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                 | 01 Oct 2020 20:35:28 |
| User entered 'UN UNK 2010' | Kaitlin Mason (b) (4)<br>(b) (4) | 11 Sep 2020 22:47:01 |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 11:15:04**

[Start date completely unknown](#)

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                 | 01 Oct 2020 20:35:28 |
| User entered '0'    | Kaitlin Mason (b) (4)<br>(b) (4) | 11 Sep 2020 22:47:01 |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 11:15:04**

[Ongoing?](#)

| Audit                  | User                             | Time (GMT)           |
|------------------------|----------------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)                 | 01 Oct 2020 20:35:28 |
| User entered 'Yes (Y)' | Kaitlin Mason (b) (4)<br>(b) (4) | 11 Sep 2020 22:47:01 |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 11:15:04**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit               | User                  | Time (GMT)           |
|---------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)      | 01 Oct 2020 20:35:28 |
| User entered empty. | Kaitlin Mason (b) (4) | 11 Sep 2020 22:47:01 |
|                     | (b) (4)               |                      |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 11:15:04**

[Was this medication taken for solicited event?](#)

| Audit                 | User                  | Time (GMT)           |
|-----------------------|-----------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)      | 01 Oct 2020 20:35:28 |
| User entered 'No (N)' | Kaitlin Mason (b) (4) | 11 Sep 2020 22:47:01 |
|                       | (b) (4)               |                      |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 11:15:04**

[Separate Dosage Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 11 Sep 2020 22:47:01 |



US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 11:15:04**

[Interval Dosage Unit Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 11 Sep 2020 22:47:01 |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 11:15:04**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User   | Time (GMT)           |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 11 Sep 2020 22:47:01 |

US3742169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:15:04

[Name of Medication](#)

| Audit                                                                                                                                                                                                                              | User                         | Time (GMT)                                   |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------|----------------------------------------------|
| User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: THYROID THERAPY, ATC: THYROID PREPARATIONS, ATC: THYROID HORMONES, PRODUCT: LEVOTHYROXINE - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)         | 01 Oct 2020 20:36:59                         |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.                                                                                                                          | Coder Import (b) (4)         | 01 Oct 2020 20:36:59                         |
| Data point term sent to Coder DataPoint Verified.                                                                                                                                                                                  | System (b) (4), (b) (6)      | 01 Oct 2020 20:35:30<br>01 Oct 2020 20:35:28 |
| User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: THYROID THERAPY, ATC: THYROID PREPARATIONS, ATC: THYROID HORMONES, PRODUCT: LEVOTHYROXINE - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)         | 11 Sep 2020 22:48:44                         |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.                                                                                                                          | Coder Import (b) (4)         | 11 Sep 2020 22:48:44                         |
| Data point term sent to Coder User entered 'LEVOTHYROXINE'                                                                                                                                                                         | System Kaitlin Mason (b) (4) | 11 Sep 2020 22:48:08<br>11 Sep 2020 22:48:04 |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 11:15:04**

[Prophylaxis](#)

| Audit                 | User                             | Time (GMT)           |
|-----------------------|----------------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)                 | 01 Oct 2020 20:35:28 |
| User entered 'No (N)' | Kaitlin Mason (b) (4)<br>(b) (4) | 11 Sep 2020 22:48:04 |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 11:15:04**

[Indication](#)

| Audit                         | User                             | Time (GMT)           |
|-------------------------------|----------------------------------|----------------------|
| DataPoint Verified.           | (b) (4), (b) (6)                 | 01 Oct 2020 20:35:28 |
| User entered 'HYPOTHYROIDISM' | Kaitlin Mason (b) (4)<br>(b) (4) | 11 Sep 2020 22:48:04 |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 11:15:04**

[Dose per administration](#)

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                 | 01 Oct 2020 20:35:28 |
| User entered '100'  | Kaitlin Mason (b) (4)<br>(b) (4) | 11 Sep 2020 22:48:04 |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 11:15:04**

[Dose unit](#)

| Audit                  | User                             | Time (GMT)           |
|------------------------|----------------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)                 | 01 Oct 2020 20:35:28 |
| User entered 'ug (ug)' | Kaitlin Mason (b) (4)<br>(b) (4) | 11 Sep 2020 22:48:04 |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 11:15:04**

[If dose unit is Other, specify](#)

| Audit               | User                  | Time (GMT)           |
|---------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)      | 01 Oct 2020 20:35:28 |
| User entered empty. | Kaitlin Mason (b) (4) | 11 Sep 2020 22:48:04 |
|                     | (b) (4)               |                      |



US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 11:15:04**

[Frequency](#)

| Audit                          | User                             | Time (GMT)           |
|--------------------------------|----------------------------------|----------------------|
| DataPoint Verified.            | (b) (4), (b) (6)                 | 01 Oct 2020 20:35:28 |
| User entered 'once daily (QD)' | Kaitlin Mason (b) (4)<br>(b) (4) | 11 Sep 2020 22:48:04 |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 11:15:04**

[If frequency is Other, specify](#)

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                 | 01 Oct 2020 20:35:28 |
| User entered empty. | Kaitlin Mason (b) (4)<br>(b) (4) | 11 Sep 2020 22:48:04 |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 11:15:04**

[Route of administration](#)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                 | 01 Oct 2020 20:35:28 |
| User entered 'Oral (ORAL)' | Kaitlin Mason (b) (4)<br>(b) (4) | 11 Sep 2020 22:48:04 |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 11:15:04**

If route of administration is Other, specify

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                 | 01 Oct 2020 20:35:28 |
| User entered empty. | Kaitlin Mason (b) (4)<br>(b) (4) | 11 Sep 2020 22:48:04 |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 11:15:04**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                 | 01 Oct 2020 20:35:28 |
| User entered 'UN UNK 1990' | Kaitlin Mason (b) (4)<br>(b) (4) | 11 Sep 2020 22:48:04 |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 11:15:04**

[Start date completely unknown](#)

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                 | 01 Oct 2020 20:35:28 |
| User entered '0'    | Kaitlin Mason (b) (4)<br>(b) (4) | 11 Sep 2020 22:48:04 |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 11:15:04**

[Ongoing?](#)

| Audit                  | User                             | Time (GMT)           |
|------------------------|----------------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)                 | 01 Oct 2020 20:35:28 |
| User entered 'Yes (Y)' | Kaitlin Mason (b) (4)<br>(b) (4) | 11 Sep 2020 22:48:04 |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 11:15:04**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                 | 01 Oct 2020 20:35:28 |
| User entered empty. | Kaitlin Mason (b) (4)<br>(b) (4) | 11 Sep 2020 22:48:04 |



US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 11:15:04**

[Was this medication taken for solicited event?](#)

| Audit                 | User                             | Time (GMT)           |
|-----------------------|----------------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)                 | 01 Oct 2020 20:35:28 |
| User entered 'No (N)' | Kaitlin Mason (b) (4)<br>(b) (4) | 11 Sep 2020 22:48:04 |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 11:15:04**

[Separate Dosage Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 11 Sep 2020 22:48:04 |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 11:15:04**

[Interval Dosage Unit Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 11 Sep 2020 22:48:04 |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 11:15:04**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User   | Time (GMT)           |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 11 Sep 2020 22:48:04 |

US3742169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:15:04

[Name of Medication](#)

| Audit                                                                                                                                                                                                                                      | User                                       | Time (GMT)                                   |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------|----------------------------------------------|
| User coded data point as ATC:<br>CARDIOVASCULAR SYSTEM, ATC: AGENTS<br>ACTING ON THE RENIN-ANGIOTENSIN<br>SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC:<br>ACE INHIBITORS, PLAIN, PRODUCT:<br>ENALAPRIL - version<br>WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4)            | 01 Oct 2020 20:37:00                         |
| User coded data point as Term Coded data point by<br>User: Coder System - version<br>WHODrug-Global-B3\\202003.                                                                                                                            | Coder Import (b) (4)<br>(b) (4)            | 01 Oct 2020 20:37:00                         |
| Data point term sent to Coder<br>DataPoint Verified.                                                                                                                                                                                       | System<br>(b) (4), (b) (6)                 | 01 Oct 2020 20:35:29<br>01 Oct 2020 20:35:28 |
| User coded data point as ATC:<br>CARDIOVASCULAR SYSTEM, ATC: AGENTS<br>ACTING ON THE RENIN-ANGIOTENSIN<br>SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC:<br>ACE INHIBITORS, PLAIN, PRODUCT:<br>ENALAPRIL - version<br>WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4)            | 11 Sep 2020 22:51:52                         |
| User coded data point as Term Coded data point by<br>User: Coder System - version<br>WHODrug-Global-B3\\202003.                                                                                                                            | Coder Import (b) (4)<br>(b) (4)            | 11 Sep 2020 22:51:52                         |
| Data point term sent to Coder<br>User entered 'ENALAPRIL'                                                                                                                                                                                  | System<br>Kaitlin Mason (b) (4)<br>(b) (4) | 11 Sep 2020 22:50:15<br>11 Sep 2020 22:50:05 |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 11:15:04**

[Prophylaxis](#)

| Audit                 | User                             | Time (GMT)           |
|-----------------------|----------------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)                 | 01 Oct 2020 20:35:28 |
| User entered 'No (N)' | Kaitlin Mason (b) (4)<br>(b) (4) | 11 Sep 2020 22:50:05 |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 11:15:04**

[Indication](#)

| Audit                       | User                             | Time (GMT)           |
|-----------------------------|----------------------------------|----------------------|
| DataPoint Verified.         | (b) (4), (b) (6)                 | 01 Oct 2020 20:35:28 |
| User entered 'HYPERTENSION' | Kaitlin Mason (b) (4)<br>(b) (4) | 11 Sep 2020 22:50:05 |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 11:15:04**

[Dose per administration](#)

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                 | 01 Oct 2020 20:35:28 |
| User entered '5'    | Kaitlin Mason (b) (4)<br>(b) (4) | 11 Sep 2020 22:50:05 |



US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 11:15:04**

[Dose unit](#)

| Audit                  | User                             | Time (GMT)           |
|------------------------|----------------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)                 | 01 Oct 2020 20:35:28 |
| User entered 'mg (mg)' | Kaitlin Mason (b) (4)<br>(b) (4) | 11 Sep 2020 22:50:05 |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 11:15:04**

If dose unit is Other, specify

| Audit               | User                  | Time (GMT)           |
|---------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)      | 01 Oct 2020 20:35:28 |
| User entered empty. | Kaitlin Mason (b) (4) | 11 Sep 2020 22:50:05 |
|                     | (b) (4)               |                      |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 11:15:04**

[Frequency](#)

| Audit                          | User                             | Time (GMT)           |
|--------------------------------|----------------------------------|----------------------|
| DataPoint Verified.            | (b) (4), (b) (6)                 | 01 Oct 2020 20:35:28 |
| User entered 'once daily (QD)' | Kaitlin Mason (b) (4)<br>(b) (4) | 11 Sep 2020 22:50:05 |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 11:15:04**

[If frequency is Other, specify](#)

| Audit               | User                  | Time (GMT)           |
|---------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)      | 01 Oct 2020 20:35:28 |
| User entered empty. | Kaitlin Mason (b) (4) | 11 Sep 2020 22:50:05 |
|                     | (b) (4)               |                      |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 11:15:04**

[Route of administration](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)      | 01 Oct 2020 20:35:28 |
| User entered 'Oral (ORAL)' | Kaitlin Mason (b) (4) | 11 Sep 2020 22:50:05 |
|                            | (b) (4)               |                      |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 11:15:04**

If route of administration is Other, specify

| Audit               | User                  | Time (GMT)           |
|---------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)      | 01 Oct 2020 20:35:28 |
| User entered empty. | Kaitlin Mason (b) (4) | 11 Sep 2020 22:50:05 |
|                     | (b) (4)               |                      |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 11:15:04**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                 | 01 Oct 2020 20:35:28 |
| User entered 'UN UNK 2018' | Kaitlin Mason (b) (4)<br>(b) (4) | 11 Sep 2020 22:50:05 |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 11:15:04**

[Start date completely unknown](#)

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                 | 01 Oct 2020 20:35:28 |
| User entered '0'    | Kaitlin Mason (b) (4)<br>(b) (4) | 11 Sep 2020 22:50:05 |



US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 11:15:04**

[Ongoing?](#)

| Audit                  | User                             | Time (GMT)           |
|------------------------|----------------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)                 | 01 Oct 2020 20:35:28 |
| User entered 'Yes (Y)' | Kaitlin Mason (b) (4)<br>(b) (4) | 11 Sep 2020 22:50:05 |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 11:15:04**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit               | User                  | Time (GMT)           |
|---------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)      | 01 Oct 2020 20:35:28 |
| User entered empty. | Kaitlin Mason (b) (4) | 11 Sep 2020 22:50:05 |
|                     | (b) (4)               |                      |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 11:15:04**

[Was this medication taken for solicited event?](#)

| Audit                 | User                  | Time (GMT)           |
|-----------------------|-----------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)      | 01 Oct 2020 20:35:28 |
| User entered 'No (N)' | Kaitlin Mason (b) (4) | 11 Sep 2020 22:50:05 |
|                       | (b) (4)               |                      |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 11:15:04**

[Separate Dosage Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 11 Sep 2020 22:50:05 |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 11:15:04**

[Interval Dosage Unit Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 11 Sep 2020 22:50:05 |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 11:15:04**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User   | Time (GMT)           |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 11 Sep 2020 22:50:05 |

US3742169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:15:04

[Name of Medication](#)

| Audit                                                                                                                                                                                                                                                                                                                                         | User                            | Time (GMT)                                   |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------|----------------------------------------------|
| User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: ADRENERGICS IN COMBINATION WITH CORTICOSTEROIDS OR OTHER DRUGS, EXCL. ANTICHOLINERGICS, PRODUCT: FLUTICASONE FUROATE;VILANTEROL TRIFENATATE, PRODUCTSYNONYM: BREO ELLIPTA - version WHODrug-Global-B3\202003. | Coder Import (b) (4)<br>(b) (4) | 29 Oct 2020 18:48:01                         |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.                                                                                                                                                                                                                                      | Coder Import (b) (4)<br>(b) (4) | 29 Oct 2020 18:48:01                         |
| Data point term sent to Coder DataPoint Un-verified.                                                                                                                                                                                                                                                                                          | System<br>(b) (4), (b) (6)      | 29 Oct 2020 18:46:55<br>29 Oct 2020 18:46:39 |
| Coding entries removed.                                                                                                                                                                                                                                                                                                                       | (b) (4), (b) (6)                | 29 Oct 2020 18:46:39                         |
| User entered 'BREO Ellipta' reason for change: Data Entry Error                                                                                                                                                                                                                                                                               | (b) (4), (b) (6)                | 29 Oct 2020 18:46:39                         |
| User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: ADRENERGICS IN COMBINATION WITH CORTICOSTEROIDS OR OTHER DRUGS, EXCL. ANTICHOLINERGICS, PRODUCT: FLUTICASONE FUROATE;VILANTEROL TRIFENATATE, PRODUCTSYNONYM: BREO ELLIPTA - version WHODrug-Global-B3\202003. | Coder Import (b) (4)<br>(b) (4) | 01 Oct 2020 20:37:00                         |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.                                                                                                                                                                                                                                      | Coder Import (b) (4)<br>(b) (4) | 01 Oct 2020 20:37:00                         |
| Data point term sent to Coder DataPoint Verified.                                                                                                                                                                                                                                                                                             | System<br>(b) (4), (b) (6)      | 01 Oct 2020 20:35:29<br>01 Oct 2020 20:35:28 |

US3742169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:15:04

[Name of Medication](#)

| Audit                                                                                                                                                                                                                                                                                                                                          | User                         | Time (GMT)                                   |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------|----------------------------------------------|
| User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: ADRENERGICS IN COMBINATION WITH CORTICOSTEROIDS OR OTHER DRUGS, EXCL. ANTICHOLINERGICS, PRODUCT: FLUTICASONE FUROATE;VILANTEROL TRIFENATATE, PRODUCTSYNONYM: BREO ELLIPTA - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)         | 11 Sep 2020 22:52:25                         |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.                                                                                                                                                                                                                                      | Coder Import (b) (4)         | 11 Sep 2020 22:52:25                         |
| User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: ADRENERGICS IN COMBINATION WITH CORTICOSTEROIDS OR OTHER DRUGS, EXCL. ANTICHOLINERGICS, PRODUCT: FLUTICASONE FUROATE;VILANTEROL TRIFENATATE, PRODUCTSYNONYM: BREO ELLIPTA - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)         | 11 Sep 2020 22:51:54                         |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.                                                                                                                                                                                                                                      | Coder Import (b) (4)         | 11 Sep 2020 22:51:54                         |
| Data point term sent to Coder User entered 'BREO'                                                                                                                                                                                                                                                                                              | System Kaitlin Mason (b) (4) | 11 Sep 2020 22:51:18<br>11 Sep 2020 22:51:02 |



US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 11:15:04**

[Prophylaxis](#)

| Audit                 | User                             | Time (GMT)           |
|-----------------------|----------------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)                 | 01 Oct 2020 20:35:28 |
| User entered 'No (N)' | Kaitlin Mason (b) (4)<br>(b) (4) | 11 Sep 2020 22:51:02 |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 11:15:04**

[Indication](#)

| Audit                 | User                             | Time (GMT)           |
|-----------------------|----------------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)                 | 01 Oct 2020 20:35:28 |
| User entered 'ASTHMA' | Kaitlin Mason (b) (4)<br>(b) (4) | 11 Sep 2020 22:51:02 |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 11:15:04**

[Dose per administration](#)

| Audit                                                                                                                                                                                                                                                                   | User                             | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------|----------------------|
| User closed query 'Per DM CLR: Please update the DOSE and UNIT entries for this combination drug to list the specific doses for each component rather than a number of puffs. Please verify the dose and unit, and update as appropriate. ' (Site from DM).             | (b) (4), (b) (6)                 | 16 Nov 2020 14:42:35 |
| Query 'Per DM CLR: Please update the DOSE and UNIT entries for this combination drug to list the specific doses for each component rather than a number of puffs. Please verify the dose and unit, and update as appropriate. ' answered with 'updated' (Site from DM). | (b) (4), (b) (6)                 | 31 Oct 2020 12:08:25 |
| User entered '100/25' reason for change: Data Entry Error                                                                                                                                                                                                               | (b) (4), (b) (6)                 | 31 Oct 2020 12:08:15 |
| DataPoint Un-verified.                                                                                                                                                                                                                                                  | (b) (4), (b) (6)                 | 29 Oct 2020 18:49:12 |
| User entered '25/' reason for change: Data Entry Error                                                                                                                                                                                                                  | (b) (4), (b) (6)                 | 29 Oct 2020 18:49:12 |
| User opened query 'Per DM CLR: Please update the DOSE and UNIT entries for this combination drug to list the specific doses for each component rather than a number of puffs. Please verify the dose and unit, and update as appropriate. ' (Site from DM).             | (b) (4), (b) (6)                 | 27 Oct 2020 13:18:38 |
| DataPoint Verified.                                                                                                                                                                                                                                                     | (b) (4), (b) (6)                 | 01 Oct 2020 20:35:28 |
| User entered '1'                                                                                                                                                                                                                                                        | Kaitlin Mason (b) (4)<br>(b) (4) | 11 Sep 2020 22:51:02 |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 11:15:04**

[Dose unit](#)

| Audit                                                      | User                             | Time (GMT)           |
|------------------------------------------------------------|----------------------------------|----------------------|
| DataPoint Un-verified.                                     | (b) (4), (b) (6)                 | 29 Oct 2020 18:46:39 |
| User entered 'ug (ug)' reason for change: Data Entry Error | (b) (4), (b) (6)                 | 29 Oct 2020 18:46:39 |
| DataPoint Verified.                                        | (b) (4), (b) (6)                 | 01 Oct 2020 20:35:28 |
| User entered 'puff (PUFF)'                                 | Kaitlin Mason (b) (4)<br>(b) (4) | 11 Sep 2020 22:51:02 |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 11:15:04**

[If dose unit is Other, specify](#)

| Audit               | User                  | Time (GMT)           |
|---------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)      | 01 Oct 2020 20:35:28 |
| User entered empty. | Kaitlin Mason (b) (4) | 11 Sep 2020 22:51:02 |
|                     | (b) (4)               |                      |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 11:15:04**

[Frequency](#)

| Audit                          | User                             | Time (GMT)           |
|--------------------------------|----------------------------------|----------------------|
| DataPoint Verified.            | (b) (4), (b) (6)                 | 01 Oct 2020 20:35:28 |
| User entered 'as needed (PRN)' | Kaitlin Mason (b) (4)<br>(b) (4) | 11 Sep 2020 22:51:02 |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 11:15:04**

[If frequency is Other, specify](#)

| Audit               | User                  | Time (GMT)           |
|---------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)      | 01 Oct 2020 20:35:28 |
| User entered empty. | Kaitlin Mason (b) (4) | 11 Sep 2020 22:51:02 |
|                     | (b) (4)               |                      |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 11:15:04**

[Route of administration](#)

| Audit                                                                 | User                             | Time (GMT)           |
|-----------------------------------------------------------------------|----------------------------------|----------------------|
| DataPoint Verified.                                                   | (b) (4), (b) (6)                 | 01 Oct 2020 20:35:28 |
| User entered 'Respiratory (Inhalation)<br>(RESPIRATORY (INHALATION))' | Kaitlin Mason (b) (4)<br>(b) (4) | 11 Sep 2020 22:51:02 |



US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 11:15:04**

If route of administration is Other, specify

| Audit               | User                  | Time (GMT)           |
|---------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)      | 01 Oct 2020 20:35:28 |
| User entered empty. | Kaitlin Mason (b) (4) | 11 Sep 2020 22:51:02 |
|                     | (b) (4)               |                      |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 11:15:04**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                 | 01 Oct 2020 20:35:28 |
| User entered 'UN Aug 2020' | Kaitlin Mason (b) (4)<br>(b) (4) | 11 Sep 2020 22:51:02 |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 11:15:04**

[Start date completely unknown](#)

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                 | 01 Oct 2020 20:35:28 |
| User entered '0'    | Kaitlin Mason (b) (4)<br>(b) (4) | 11 Sep 2020 22:51:02 |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 11:15:04**

[Ongoing?](#)

| Audit                  | User                             | Time (GMT)           |
|------------------------|----------------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)                 | 01 Oct 2020 20:35:28 |
| User entered 'Yes (Y)' | Kaitlin Mason (b) (4)<br>(b) (4) | 11 Sep 2020 22:51:02 |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 11:15:04**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit               | User                  | Time (GMT)           |
|---------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)      | 01 Oct 2020 20:35:28 |
| User entered empty. | Kaitlin Mason (b) (4) | 11 Sep 2020 22:51:02 |
|                     | (b) (4)               |                      |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 11:15:04**

[Was this medication taken for solicited event?](#)

| Audit                 | User                  | Time (GMT)           |
|-----------------------|-----------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)      | 01 Oct 2020 20:35:28 |
| User entered 'No (N)' | Kaitlin Mason (b) (4) | 11 Sep 2020 22:51:02 |
|                       | (b) (4)               |                      |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 11:15:04**

[Separate Dosage Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 11 Sep 2020 22:51:02 |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 11:15:04**

[Interval Dosage Unit Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 11 Sep 2020 22:51:02 |



US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 11:15:04**

[Interval Dosage Definition \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 11 Sep 2020 22:51:02 |

US3742169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:15:04

[Name of Medication](#)

| Audit                                                                                                                                                                                                                                                                      | User                                       | Time (GMT)                                   |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------|----------------------------------------------|
| User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: SALBUTAMOL, PRODUCTSYNONYM: ALBUTEROL [SALBUTAMOL] - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4)            | 01 Oct 2020 20:36:59                         |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.                                                                                                                                                                  | Coder Import (b) (4)<br>(b) (4)            | 01 Oct 2020 20:36:59                         |
| Data point term sent to Coder DataPoint Verified.                                                                                                                                                                                                                          | System<br>(b) (4), (b) (6)                 | 01 Oct 2020 20:35:30<br>01 Oct 2020 20:35:28 |
| User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: SALBUTAMOL, PRODUCTSYNONYM: ALBUTEROL [SALBUTAMOL] - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4)            | 11 Sep 2020 22:52:40                         |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.                                                                                                                                                                  | Coder Import (b) (4)<br>(b) (4)            | 11 Sep 2020 22:52:40                         |
| Data point term sent to Coder User entered 'ALBUTEROL'                                                                                                                                                                                                                     | System<br>Kaitlin Mason (b) (4)<br>(b) (4) | 11 Sep 2020 22:52:20<br>11 Sep 2020 22:52:06 |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 11:15:04**

[Prophylaxis](#)

| Audit                 | User                             | Time (GMT)           |
|-----------------------|----------------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)                 | 01 Oct 2020 20:35:28 |
| User entered 'No (N)' | Kaitlin Mason (b) (4)<br>(b) (4) | 11 Sep 2020 22:52:06 |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 11:15:04**

[Indication](#)

| Audit                 | User                             | Time (GMT)           |
|-----------------------|----------------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)                 | 01 Oct 2020 20:35:28 |
| User entered 'ASTHMA' | Kaitlin Mason (b) (4)<br>(b) (4) | 11 Sep 2020 22:52:06 |

US3742169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:15:04

[Dose per administration](#)

| Audit                                                                                                                                                                                      | User                             | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------|----------------------|
| User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of puff count. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).             | (b) (4), (b) (6)                 | 16 Nov 2020 14:42:41 |
| Query 'Per DM CLR: Please provide the actual dose for this medication instead of puff count. Update the Dose and Dose Unit fields as appropriate.' answered with 'Updated' (Site from DM). | (b) (4), (b) (6)                 | 29 Oct 2020 18:35:30 |
| DataPoint Un-verified.                                                                                                                                                                     | (b) (4), (b) (6)                 | 29 Oct 2020 18:34:20 |
| User entered '90' reason for change: Data Entry Error                                                                                                                                      | (b) (4), (b) (6)                 | 29 Oct 2020 18:34:20 |
| User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of puff count. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).             | (b) (4), (b) (6)                 | 27 Oct 2020 13:23:49 |
| DataPoint Verified.                                                                                                                                                                        | (b) (4), (b) (6)                 | 01 Oct 2020 20:35:28 |
| User entered '1'                                                                                                                                                                           | Kaitlin Mason (b) (4)<br>(b) (4) | 11 Sep 2020 22:52:06 |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 11:15:04**

[Dose unit](#)

| Audit                                                      | User                             | Time (GMT)           |
|------------------------------------------------------------|----------------------------------|----------------------|
| DataPoint Un-verified.                                     | (b) (4), (b) (6)                 | 29 Oct 2020 18:34:20 |
| User entered 'ug (ug)' reason for change: Data Entry Error | (b) (4), (b) (6)                 | 29 Oct 2020 18:34:20 |
| DataPoint Verified.                                        | (b) (4), (b) (6)                 | 01 Oct 2020 20:35:28 |
| User entered 'puff (PUFF)'                                 | Kaitlin Mason (b) (4)<br>(b) (4) | 11 Sep 2020 22:52:06 |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 11:15:04**

[If dose unit is Other, specify](#)

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                 | 01 Oct 2020 20:35:28 |
| User entered empty. | Kaitlin Mason (b) (4)<br>(b) (4) | 11 Sep 2020 22:52:06 |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 11:15:04**

[Frequency](#)

| Audit                          | User                             | Time (GMT)           |
|--------------------------------|----------------------------------|----------------------|
| DataPoint Verified.            | (b) (4), (b) (6)                 | 01 Oct 2020 20:35:28 |
| User entered 'as needed (PRN)' | Kaitlin Mason (b) (4)<br>(b) (4) | 11 Sep 2020 22:52:06 |



US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 11:15:04**

[If frequency is Other, specify](#)

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                 | 01 Oct 2020 20:35:28 |
| User entered empty. | Kaitlin Mason (b) (4)<br>(b) (4) | 11 Sep 2020 22:52:06 |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 11:15:04**

[Route of administration](#)

| Audit                                                                 | User                             | Time (GMT)           |
|-----------------------------------------------------------------------|----------------------------------|----------------------|
| DataPoint Verified.                                                   | (b) (4), (b) (6)                 | 01 Oct 2020 20:35:28 |
| User entered 'Respiratory (Inhalation)<br>(RESPIRATORY (INHALATION))' | Kaitlin Mason (b) (4)<br>(b) (4) | 11 Sep 2020 22:52:06 |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 11:15:04**

If route of administration is Other, specify

| Audit               | User                  | Time (GMT)           |
|---------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)      | 01 Oct 2020 20:35:28 |
| User entered empty. | Kaitlin Mason (b) (4) | 11 Sep 2020 22:52:06 |
|                     | (b) (4)               |                      |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 11:15:04**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                 | 01 Oct 2020 20:35:28 |
| User entered 'UN UNK 2000' | Kaitlin Mason (b) (4)<br>(b) (4) | 11 Sep 2020 22:52:06 |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 11:15:04**

[Start date completely unknown](#)

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                 | 01 Oct 2020 20:35:28 |
| User entered '0'    | Kaitlin Mason (b) (4)<br>(b) (4) | 11 Sep 2020 22:52:06 |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 11:15:04**

[Ongoing?](#)

| Audit                  | User                             | Time (GMT)           |
|------------------------|----------------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)                 | 01 Oct 2020 20:35:28 |
| User entered 'Yes (Y)' | Kaitlin Mason (b) (4)<br>(b) (4) | 11 Sep 2020 22:52:06 |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 11:15:04**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit               | User                  | Time (GMT)           |
|---------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)      | 01 Oct 2020 20:35:28 |
| User entered empty. | Kaitlin Mason (b) (4) | 11 Sep 2020 22:52:06 |
|                     | (b) (4)               |                      |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 11:15:04**

[Was this medication taken for solicited event?](#)

| Audit                 | User                  | Time (GMT)           |
|-----------------------|-----------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)      | 01 Oct 2020 20:35:28 |
| User entered 'No (N)' | Kaitlin Mason (b) (4) | 11 Sep 2020 22:52:06 |
|                       | (b) (4)               |                      |



US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 11:15:04**

[Separate Dosage Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 11 Sep 2020 22:52:06 |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 11:15:04**

[Interval Dosage Unit Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 11 Sep 2020 22:52:06 |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 11:15:04**

[Interval Dosage Definition \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 11 Sep 2020 22:52:06 |

US3742169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:15:04

[Name of Medication](#)

| Audit                                                                                                                                                                                                                   | User                  | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|----------------------|
| User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: PIPERAZINE DERIVATIVES, PRODUCT: LEVOCETIRIZINE - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)  | 29 Oct 2020 18:39:43 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.                                                                                                               | Coder Import (b) (4)  | 29 Oct 2020 18:39:43 |
| Data point term sent to Coder                                                                                                                                                                                           | System                | 29 Oct 2020 18:39:36 |
| Coding entries removed.                                                                                                                                                                                                 | (b) (4), (b) (6)      | 29 Oct 2020 18:39:10 |
| User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: PIPERAZINE DERIVATIVES, PRODUCT: LEVOCETIRIZINE - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)  | 01 Oct 2020 20:37:00 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.                                                                                                               | Coder Import (b) (4)  | 01 Oct 2020 20:37:00 |
| Data point term sent to Coder                                                                                                                                                                                           | System                | 01 Oct 2020 20:35:32 |
| DataPoint Verified.                                                                                                                                                                                                     | (b) (4), (b) (6)      | 01 Oct 2020 20:35:28 |
| User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: PIPERAZINE DERIVATIVES, PRODUCT: LEVOCETIRIZINE - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)  | 11 Sep 2020 22:53:41 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.                                                                                                               | Coder Import (b) (4)  | 11 Sep 2020 22:53:41 |
| Data point term sent to Coder                                                                                                                                                                                           | System                | 11 Sep 2020 22:53:21 |
| User entered 'LEVOCETIRIZINE'                                                                                                                                                                                           | Kaitlin Mason (b) (4) | 11 Sep 2020 22:53:02 |
|                                                                                                                                                                                                                         | (b) (4)               |                      |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 11:15:04**

[Prophylaxis](#)

| Audit                 | User                             | Time (GMT)           |
|-----------------------|----------------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)                 | 01 Oct 2020 20:35:28 |
| User entered 'No (N)' | Kaitlin Mason (b) (4)<br>(b) (4) | 11 Sep 2020 22:53:02 |

US3742169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:15:04

[Indication](#)

| Audit                                                                                                                                                                                                                        | User                  | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|----------------------|
| User closed query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM). | (b) (4), (b) (6)      | 16 Nov 2020 14:42:54 |
| Query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.'                             | (b) (4), (b) (6)      | 29 Oct 2020 18:39:25 |
| answered with 'Updated' (Site from DM).                                                                                                                                                                                      |                       |                      |
| DataPoint Un-verified.                                                                                                                                                                                                       | (b) (4), (b) (6)      | 29 Oct 2020 18:39:10 |
| User entered 'ENVIRONMENTAL ALLERGIES' reason for change: Data Entry Error                                                                                                                                                   | (b) (4), (b) (6)      | 29 Oct 2020 18:39:10 |
| User opened query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM). | (b) (4), (b) (6)      | 28 Oct 2020 16:18:33 |
| DataPoint Verified.                                                                                                                                                                                                          | (b) (4), (b) (6)      | 01 Oct 2020 20:35:28 |
| User entered 'SEASONAL ALLERGIES'                                                                                                                                                                                            | Kaitlin Mason (b) (4) | 11 Sep 2020 22:53:02 |
|                                                                                                                                                                                                                              | (b) (4)               |                      |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 11:15:04**

[Dose per administration](#)

| Audit               | User                  | Time (GMT)           |
|---------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)      | 01 Oct 2020 20:35:28 |
| User entered '5'    | Kaitlin Mason (b) (4) | 11 Sep 2020 22:53:02 |
|                     | (b) (4)               |                      |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 11:15:04**

[Dose unit](#)

| Audit                  | User                             | Time (GMT)           |
|------------------------|----------------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)                 | 01 Oct 2020 20:35:28 |
| User entered 'mg (mg)' | Kaitlin Mason (b) (4)<br>(b) (4) | 11 Sep 2020 22:53:02 |



US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 11:15:04**

If dose unit is Other, specify

| Audit               | User                  | Time (GMT)           |
|---------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)      | 01 Oct 2020 20:35:28 |
| User entered empty. | Kaitlin Mason (b) (4) | 11 Sep 2020 22:53:02 |
|                     | (b) (4)               |                      |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 11:15:04**

[Frequency](#)

| Audit                          | User                             | Time (GMT)           |
|--------------------------------|----------------------------------|----------------------|
| DataPoint Verified.            | (b) (4), (b) (6)                 | 01 Oct 2020 20:35:28 |
| User entered 'once daily (QD)' | Kaitlin Mason (b) (4)<br>(b) (4) | 11 Sep 2020 22:53:02 |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 11:15:04**

[If frequency is Other, specify](#)

| Audit               | User                  | Time (GMT)           |
|---------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)      | 01 Oct 2020 20:35:28 |
| User entered empty. | Kaitlin Mason (b) (4) | 11 Sep 2020 22:53:02 |
|                     | (b) (4)               |                      |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 11:15:04**

[Route of administration](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)      | 01 Oct 2020 20:35:28 |
| User entered 'Oral (ORAL)' | Kaitlin Mason (b) (4) | 11 Sep 2020 22:53:02 |
|                            | (b) (4)               |                      |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 11:15:04**

If route of administration is Other, specify

| Audit               | User                  | Time (GMT)           |
|---------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)      | 01 Oct 2020 20:35:28 |
| User entered empty. | Kaitlin Mason (b) (4) | 11 Sep 2020 22:53:02 |
|                     | (b) (4)               |                      |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 11:15:04**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                 | 01 Oct 2020 20:35:28 |
| User entered 'UN UNK 2018' | Kaitlin Mason (b) (4)<br>(b) (4) | 11 Sep 2020 22:53:02 |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 11:15:04**

[Start date completely unknown](#)

| Audit               | User                  | Time (GMT)           |
|---------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)      | 01 Oct 2020 20:35:28 |
| User entered '0'    | Kaitlin Mason (b) (4) | 11 Sep 2020 22:53:02 |
|                     | (b) (4)               |                      |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 11:15:04**

[Ongoing?](#)

| Audit                  | User                             | Time (GMT)           |
|------------------------|----------------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)                 | 01 Oct 2020 20:35:28 |
| User entered 'Yes (Y)' | Kaitlin Mason (b) (4)<br>(b) (4) | 11 Sep 2020 22:53:02 |



US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 11:15:04**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                 | 01 Oct 2020 20:35:28 |
| User entered empty. | Kaitlin Mason (b) (4)<br>(b) (4) | 11 Sep 2020 22:53:02 |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 11:15:04**

[Was this medication taken for solicited event?](#)

| Audit                 | User                  | Time (GMT)           |
|-----------------------|-----------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)      | 01 Oct 2020 20:35:28 |
| User entered 'No (N)' | Kaitlin Mason (b) (4) | 11 Sep 2020 22:53:02 |
|                       | (b) (4)               |                      |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 11:15:04**

[Separate Dosage Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 11 Sep 2020 22:53:02 |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 11:15:04**

[Interval Dosage Unit Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 11 Sep 2020 22:53:02 |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 11:15:04**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User   | Time (GMT)           |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 11 Sep 2020 22:53:02 |

US3742169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:15:04

[Name of Medication](#)

| Audit                                                                                                                                                                                                                                                     | User                                       | Time (GMT)                                   |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------|----------------------------------------------|
| User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER SYSTEMIC DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: LEUKOTRIENE RECEPTOR ANTAGONISTS, PRODUCT: MONTELUKAST - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4)            | 01 Oct 2020 20:37:00                         |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.                                                                                                                                                 | Coder Import (b) (4)<br>(b) (4)            | 01 Oct 2020 20:37:00                         |
| Data point term sent to Coder DataPoint Verified.                                                                                                                                                                                                         | System<br>(b) (4), (b) (6)                 | 01 Oct 2020 20:35:32<br>01 Oct 2020 20:35:28 |
| User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER SYSTEMIC DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: LEUKOTRIENE RECEPTOR ANTAGONISTS, PRODUCT: MONTELUKAST - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4)            | 11 Sep 2020 22:56:42                         |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.                                                                                                                                                 | Coder Import (b) (4)<br>(b) (4)            | 11 Sep 2020 22:56:42                         |
| Data point term sent to Coder User entered 'MONTELUKAST'                                                                                                                                                                                                  | System<br>Kaitlin Mason (b) (4)<br>(b) (4) | 11 Sep 2020 22:55:23<br>11 Sep 2020 22:54:25 |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 11:15:04**

[Prophylaxis](#)

| Audit                 | User                  | Time (GMT)           |
|-----------------------|-----------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)      | 01 Oct 2020 20:35:28 |
| User entered 'No (N)' | Kaitlin Mason (b) (4) | 11 Sep 2020 22:54:25 |
|                       | (b) (4)               |                      |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 11:15:04**

[Indication](#)

| Audit                                  | User                             | Time (GMT)           |
|----------------------------------------|----------------------------------|----------------------|
| DataPoint Verified.                    | (b) (4), (b) (6)                 | 01 Oct 2020 20:35:28 |
| User entered 'ENVIRONMENTAL ALLERGIES' | Kaitlin Mason (b) (4)<br>(b) (4) | 11 Sep 2020 22:54:25 |



US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 11:15:04**

[Dose per administration](#)

| Audit               | User                  | Time (GMT)           |
|---------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)      | 01 Oct 2020 20:35:28 |
| User entered '10'   | Kaitlin Mason (b) (4) | 11 Sep 2020 22:54:25 |
|                     | (b) (4)               |                      |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 11:15:04**

[Dose unit](#)

| Audit                  | User                             | Time (GMT)           |
|------------------------|----------------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)                 | 01 Oct 2020 20:35:28 |
| User entered 'mg (mg)' | Kaitlin Mason (b) (4)<br>(b) (4) | 11 Sep 2020 22:54:25 |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 11:15:04**

[If dose unit is Other, specify](#)

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                 | 01 Oct 2020 20:35:28 |
| User entered empty. | Kaitlin Mason (b) (4)<br>(b) (4) | 11 Sep 2020 22:54:25 |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 11:15:04**

[Frequency](#)

| Audit                          | User                  | Time (GMT)           |
|--------------------------------|-----------------------|----------------------|
| DataPoint Verified.            | (b) (4), (b) (6)      | 01 Oct 2020 20:35:28 |
| User entered 'once daily (QD)' | Kaitlin Mason (b) (4) | 11 Sep 2020 22:54:25 |
|                                | (b) (4)               |                      |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 11:15:04**

[If frequency is Other, specify](#)

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                 | 01 Oct 2020 20:35:28 |
| User entered empty. | Kaitlin Mason (b) (4)<br>(b) (4) | 11 Sep 2020 22:54:25 |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 11:15:04**

[Route of administration](#)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                 | 01 Oct 2020 20:35:28 |
| User entered 'Oral (ORAL)' | Kaitlin Mason (b) (4)<br>(b) (4) | 11 Sep 2020 22:54:25 |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 11:15:04**

If route of administration is Other, specify

| Audit               | User                  | Time (GMT)           |
|---------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)      | 01 Oct 2020 20:35:28 |
| User entered empty. | Kaitlin Mason (b) (4) | 11 Sep 2020 22:54:25 |
|                     | (b) (4)               |                      |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 11:15:04**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                 | 01 Oct 2020 20:35:28 |
| User entered 'UN UNK 1990' | Kaitlin Mason (b) (4)<br>(b) (4) | 11 Sep 2020 22:54:25 |



US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 11:15:04**

[Start date completely unknown](#)

| Audit               | User                  | Time (GMT)           |
|---------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)      | 01 Oct 2020 20:35:28 |
| User entered '0'    | Kaitlin Mason (b) (4) | 11 Sep 2020 22:54:25 |
|                     | (b) (4)               |                      |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 11:15:04**

[Ongoing?](#)

| Audit                  | User                             | Time (GMT)           |
|------------------------|----------------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)                 | 01 Oct 2020 20:35:28 |
| User entered 'Yes (Y)' | Kaitlin Mason (b) (4)<br>(b) (4) | 11 Sep 2020 22:54:25 |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 11:15:04**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit               | User                  | Time (GMT)           |
|---------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)      | 01 Oct 2020 20:35:28 |
| User entered empty. | Kaitlin Mason (b) (4) | 11 Sep 2020 22:54:25 |
|                     | (b) (4)               |                      |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 11:15:04**

[Was this medication taken for solicited event?](#)

| Audit                 | User                  | Time (GMT)           |
|-----------------------|-----------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)      | 01 Oct 2020 20:35:28 |
| User entered 'No (N)' | Kaitlin Mason (b) (4) | 11 Sep 2020 22:54:25 |
|                       | (b) (4)               |                      |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 11:15:04**

[Separate Dosage Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 11 Sep 2020 22:54:25 |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 11:15:04**

[Interval Dosage Unit Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 11 Sep 2020 22:54:25 |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 11:15:04**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User   | Time (GMT)           |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 11 Sep 2020 22:54:25 |

US3742169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:15:04

[Name of Medication](#)

| Audit                                                                                                                                                                                                              | User                            | Time (GMT)                                   |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------|----------------------------------------------|
| User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: BULK-FORMING LAXATIVES, PRODUCT: FIBRE, DIETARY - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4) | 01 Oct 2020 20:37:00                         |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.                                                                                                          | Coder Import (b) (4)<br>(b) (4) | 01 Oct 2020 20:37:00                         |
| Data point term sent to Coder DataPoint Verified.                                                                                                                                                                  | System<br>(b) (4), (b) (6)      | 01 Oct 2020 20:35:30<br>01 Oct 2020 20:35:28 |
| User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: BULK-FORMING LAXATIVES, PRODUCT: FIBRE, DIETARY - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4) | 25 Sep 2020 16:53:36                         |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.                                                                                                          | Coder Import (b) (4)<br>(b) (4) | 25 Sep 2020 16:53:36                         |
| Data point term sent to Coder User entered 'FIBER GUMMIES'                                                                                                                                                         | System<br>(b) (4), (b) (6)      | 25 Sep 2020 15:57:12<br>25 Sep 2020 15:57:11 |



US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 11:15:04**

[Prophylaxis](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 01 Oct 2020 20:35:28 |
| User entered 'No (N)' | (b) (4), (b) (6) | 25 Sep 2020 15:57:11 |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 11:15:04**

[Indication](#)

| Audit                       | User             | Time (GMT)           |
|-----------------------------|------------------|----------------------|
| DataPoint Verified.         | (b) (4), (b) (6) | 01 Oct 2020 20:35:28 |
| User entered 'CONSTIPATION' | (b) (4), (b) (6) | 25 Sep 2020 15:57:11 |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 11:15:04**

[Dose per administration](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 20:35:28 |
| User entered '2'    | (b) (4), (b) (6) | 25 Sep 2020 15:57:11 |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 11:15:04**

[Dose unit](#)

| Audit                        | User             | Time (GMT)           |
|------------------------------|------------------|----------------------|
| DataPoint Verified.          | (b) (4), (b) (6) | 01 Oct 2020 20:35:28 |
| User entered 'Other (OTHER)' | (b) (4), (b) (6) | 25 Sep 2020 15:57:11 |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 11:15:04**

[If dose unit is Other, specify](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 01 Oct 2020 20:35:28 |
| User entered 'GUMMIES' | (b) (4), (b) (6) | 25 Sep 2020 15:57:11 |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 11:15:04**

[Frequency](#)

| Audit                          | User             | Time (GMT)           |
|--------------------------------|------------------|----------------------|
| DataPoint Verified.            | (b) (4), (b) (6) | 01 Oct 2020 20:35:28 |
| User entered 'once daily (QD)' | (b) (4), (b) (6) | 25 Sep 2020 15:57:11 |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 11:15:04**

[If frequency is Other, specify](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 20:35:28 |
| User entered empty. | (b) (4), (b) (6) | 25 Sep 2020 15:57:11 |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 11:15:04**

[Route of administration](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 01 Oct 2020 20:35:28 |
| User entered 'Oral (ORAL)' | (b) (4), (b) (6) | 25 Sep 2020 15:57:11 |



US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 11:15:04**

If route of administration is Other, specify

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 20:35:28 |
| User entered empty. | (b) (4), (b) (6) | 25 Sep 2020 15:57:11 |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 11:15:04**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 01 Oct 2020 20:35:28 |
| User entered '15 Sep 2020' | (b) (4), (b) (6) | 25 Sep 2020 15:57:11 |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 11:15:04**

[Start date completely unknown](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 20:35:28 |
| User entered '0'    | (b) (4), (b) (6) | 25 Sep 2020 15:57:11 |

US3742169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:15:04

[Ongoing?](#)

| Audit                                                                                                                                                                                                                                                                                                   | User                             | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------|----------------------|
| User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).                                               | (b) (4), (b) (6)                 | 16 Nov 2020 14:49:15 |
| Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' answered with 'CONTINUES TO TAKE TO PREVENT CONSTIPATION' (Site from DM). | Kaitlin Mason (b) (4)<br>(b) (4) | 27 Oct 2020 17:06:31 |
| User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).                                               | (b) (4), (b) (6)                 | 26 Oct 2020 12:28:45 |
| Data hard unlocked.                                                                                                                                                                                                                                                                                     | (b) (4), (b) (6)                 | 26 Oct 2020 12:28:37 |
| Data hard locked.                                                                                                                                                                                                                                                                                       | (b) (4), (b) (6)                 | 26 Oct 2020 12:28:33 |
| DataPoint Verified.                                                                                                                                                                                                                                                                                     | (b) (4), (b) (6)                 | 01 Oct 2020 20:35:28 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                                                                                  | (b) (4), (b) (6)                 | 25 Sep 2020 15:57:11 |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 11:15:04**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 20:35:28 |
| User entered empty. | (b) (4), (b) (6) | 25 Sep 2020 15:57:11 |

US3742169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:15:04

[Was this medication taken for solicited event?](#)

| Audit                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | User                             | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------|----------------------|
| User closed query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body. Please review and update as appropriate. Otherwise, provide clarification.' (Site from DM). DataPoint Verified.                         | (b) (4), (b) (6)                 | 16 Nov 2020 14:49:13 |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | (b) (4), (b) (6)                 | 28 Oct 2020 15:59:30 |
| Query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body. Please review and update as appropriate. Otherwise, provide clarification.' answered with 'ENTERED IN ERROR' (Site from DM). DataPoint Un-verified. | Kaitlin Mason (b) (4)<br>(b) (4) | 27 Oct 2020 17:06:44 |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | Kaitlin Mason (b) (4)<br>(b) (4) | 27 Oct 2020 17:06:37 |
| User entered 'No (N)' reason for change: Data Entry Error                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | Kaitlin Mason (b) (4)<br>(b) (4) | 27 Oct 2020 17:06:37 |
| User opened query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body. Please review and update as appropriate. Otherwise, provide clarification.' (Site from DM). DataPoint Verified.                         | (b) (4), (b) (6)                 | 26 Oct 2020 12:28:14 |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | (b) (4), (b) (6)                 | 01 Oct 2020 20:35:28 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | (b) (4), (b) (6)                 | 25 Sep 2020 15:57:11 |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 11:15:04**

[Separate Dosage Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 25 Sep 2020 15:57:11 |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 11:15:04**

[Interval Dosage Unit Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 25 Sep 2020 15:57:11 |



US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 11:15:04**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User   | Time (GMT)           |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 25 Sep 2020 15:57:11 |

US3742169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:15:04

[Name of Medication](#)

| Audit                                                                                                                                                                                                                                                                                                                                                              | User                             | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------|----------------------|
| User coded data point as ATC:<br>CARDIOVASCULAR SYSTEM, ATC:<br>VASOPROTECTIVES, ATC: AGENTS FOR<br>TREATMENT OF HEMORRHOIDS AND ANAL<br>FISSURES FOR TOPICAL USE, PRODUCT:<br>PHENYLEPHRINE<br>HYDROCHLORIDE;THEOBROMA CACAO OIL,<br>PRODUCTSYNONYM: PREPARATION H<br>[PHENYLEPHRINE<br>HYDROCHLORIDE;THEOBROMA CACAO OIL]<br>- version WHODrug-Global-B3\202003. | Coder Import (b) (4)<br>(b) (4)  | 13 Nov 2020 18:36:47 |
| User coded data point as Term Coded data point by<br>User: (b) (6) - version<br>WHODrug-Global-B3\202003.                                                                                                                                                                                                                                                          | Coder Import (b) (4)<br>(b) (4)  | 13 Nov 2020 18:36:47 |
| DataPoint Verified.                                                                                                                                                                                                                                                                                                                                                | (b) (4), (b) (6)                 | 28 Oct 2020 15:59:30 |
| Data point term sent to Coder                                                                                                                                                                                                                                                                                                                                      | System                           | 27 Oct 2020 17:05:31 |
| DataPoint Un-verified.                                                                                                                                                                                                                                                                                                                                             | Kaitlin Mason (b) (4)<br>(b) (4) | 27 Oct 2020 17:05:14 |
| User entered 'PHENYLEPHRINE/ COCOA<br>BUTTER 0.25/88% SUPPOSITORIES' reason for<br>change: Data Entry Error                                                                                                                                                                                                                                                        | Kaitlin Mason (b) (4)<br>(b) (4) | 27 Oct 2020 17:05:14 |
| Data point term sent to Coder                                                                                                                                                                                                                                                                                                                                      | System                           | 01 Oct 2020 20:35:30 |
| DataPoint Verified.                                                                                                                                                                                                                                                                                                                                                | (b) (4), (b) (6)                 | 01 Oct 2020 20:35:28 |
| Data point term sent to Coder                                                                                                                                                                                                                                                                                                                                      | System                           | 25 Sep 2020 16:00:17 |
| User entered 'PHENYLEPHRINE/ COCOA<br>BUTTER SUPPOSITORIES'                                                                                                                                                                                                                                                                                                        | (b) (4), (b) (6)                 | 25 Sep 2020 15:59:51 |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 11:15:04**

[Prophylaxis](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 01 Oct 2020 20:35:28 |
| User entered 'No (N)' | (b) (4), (b) (6) | 25 Sep 2020 15:59:51 |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 11:15:04**

[Indication](#)

| Audit                       | User             | Time (GMT)           |
|-----------------------------|------------------|----------------------|
| DataPoint Verified.         | (b) (4), (b) (6) | 01 Oct 2020 20:35:28 |
| User entered 'CONSTIPATION' | (b) (4), (b) (6) | 25 Sep 2020 15:59:51 |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 11:15:04**

[Dose per administration](#)

| Audit                                                                                                                                                                                                                                                                                                                                         | User                  | Time (GMT)           |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|----------------------|
| User closed query 'Per DM CLR: Please provide the strength of this medication in the medication name (PHENYLEPHRINE/ COCOA BUTTER SUPPOSITORIES 0.25/88%), and consider recording the number of applications instead (e.g. dose=1; unit=application). Review and amend as appropriate.' (Site from DM).<br>DataPoint Verified.                | (b) (4), (b) (6)      | 17 Nov 2020 07:11:32 |
| Query 'Per DM CLR: Please provide the strength of this medication in the medication name (PHENYLEPHRINE/ COCOA BUTTER SUPPOSITORIES 0.25/88%), and consider recording the number of applications instead (e.g. dose=1; unit=application). Review and amend as appropriate.' answered with 'UPDATED' (Site from DM).<br>DataPoint Un-verified. | Kaitlin Mason (b) (4) | 27 Oct 2020 17:05:21 |
| User entered '1' reason for change: Data Entry Error                                                                                                                                                                                                                                                                                          | Kaitlin Mason (b) (4) | 27 Oct 2020 17:05:14 |
| User opened query 'Per DM CLR: Please provide the strength of this medication in the medication name (PHENYLEPHRINE/ COCOA BUTTER SUPPOSITORIES 0.25/88%), and consider recording the number of applications instead (e.g. dose=1; unit=application). Review and amend as appropriate.' (Site from DM).<br>DataPoint Verified.                | (b) (4), (b) (6)      | 26 Oct 2020 12:30:55 |
| User entered '0.25/ 88'                                                                                                                                                                                                                                                                                                                       | (b) (4), (b) (6)      | 01 Oct 2020 20:35:28 |
|                                                                                                                                                                                                                                                                                                                                               | (b) (4), (b) (6)      | 25 Sep 2020 15:59:51 |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 11:15:04**

[Dose unit](#)

| Audit                        | User             | Time (GMT)           |
|------------------------------|------------------|----------------------|
| DataPoint Verified.          | (b) (4), (b) (6) | 01 Oct 2020 20:35:28 |
| User entered 'Other (OTHER)' | (b) (4), (b) (6) | 25 Sep 2020 15:59:51 |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 11:15:04**

If dose unit is Other, specify

| Audit                                         | User                  | Time (GMT)           |
|-----------------------------------------------|-----------------------|----------------------|
| DataPoint Verified.                           | (b) (4), (b) (6)      | 28 Oct 2020 15:59:30 |
| DataPoint Un-verified.                        | Kaitlin Mason (b) (4) | 27 Oct 2020 17:05:14 |
| User entered 'APPLICATION' reason for change: | (b) (4)               |                      |
| Data Entry Error                              | Kaitlin Mason (b) (4) | 27 Oct 2020 17:05:14 |
| DataPoint Verified.                           | (b) (4)               |                      |
|                                               | (b) (4), (b) (6)      | 01 Oct 2020 20:35:28 |
| User entered 'PERCENT'                        | (b) (4), (b) (6)      | 25 Sep 2020 15:59:51 |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 11:15:04**

[Frequency](#)

| Audit                          | User             | Time (GMT)           |
|--------------------------------|------------------|----------------------|
| DataPoint Verified.            | (b) (4), (b) (6) | 01 Oct 2020 20:35:28 |
| User entered 'as needed (PRN)' | (b) (4), (b) (6) | 25 Sep 2020 15:59:51 |



US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 11:15:04**

[If frequency is Other, specify](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 20:35:28 |
| User entered empty. | (b) (4), (b) (6) | 25 Sep 2020 15:59:51 |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 11:15:04**

[Route of administration](#)

| Audit                          | User             | Time (GMT)           |
|--------------------------------|------------------|----------------------|
| DataPoint Verified.            | (b) (4), (b) (6) | 01 Oct 2020 20:35:28 |
| User entered 'Rectal (RECTAL)' | (b) (4), (b) (6) | 25 Sep 2020 15:59:51 |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 11:15:04**

If route of administration is Other, specify

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 20:35:28 |
| User entered empty. | (b) (4), (b) (6) | 25 Sep 2020 15:59:51 |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 11:15:04**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 01 Oct 2020 20:35:28 |
| User entered '16 Sep 2020' | (b) (4), (b) (6) | 25 Sep 2020 15:59:51 |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 11:15:04**

[Start date completely unknown](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 20:35:28 |
| User entered '0'    | (b) (4), (b) (6) | 25 Sep 2020 15:59:51 |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 11:15:04**

[Ongoing?](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 01 Oct 2020 20:35:28 |
| User entered 'No (N)' | (b) (4), (b) (6) | 25 Sep 2020 15:59:51 |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 11:15:04**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 01 Oct 2020 20:35:28 |
| User entered '16 Sep 2020' | (b) (4), (b) (6) | 25 Sep 2020 15:59:51 |

US3742169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:15:04

[Was this medication taken for solicited event?](#)

| Audit                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | User                  | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|----------------------|
| User closed query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body. Please review and update as appropriate. Otherwise, provide clarification.' (Site from DM). DataPoint Verified.                         | (b) (4), (b) (6)      | 17 Nov 2020 07:12:43 |
| Query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body. Please review and update as appropriate. Otherwise, provide clarification.' answered with 'ENTERED IN ERROR' (Site from DM). DataPoint Un-verified. | Kaitlin Mason (b) (4) | 27 Oct 2020 17:05:29 |
| User entered 'No (N)' reason for change: Data Entry Error                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | Kaitlin Mason (b) (4) | 27 Oct 2020 17:05:14 |
| User opened query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body. Please review and update as appropriate. Otherwise, provide clarification.' (Site from DM). DataPoint Verified.                         | (b) (4), (b) (6)      | 26 Oct 2020 12:30:22 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | (b) (4), (b) (6)      | 01 Oct 2020 20:35:28 |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | (b) (4), (b) (6)      | 25 Sep 2020 15:59:51 |



US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 11:15:04**

[Separate Dosage Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 25 Sep 2020 15:59:51 |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 11:15:04**

[Interval Dosage Unit Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 25 Sep 2020 15:59:51 |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 11:15:04**

[Interval Dosage Definition \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 25 Sep 2020 15:59:51 |

US3742169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:15:04

[Name of Medication](#)

| Audit                                                                                                                                                                                                    | User                                       | Time (GMT)                                   |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------|----------------------------------------------|
| User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4)            | 22 Nov 2020 05:42:09                         |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.                                                                                                     | Coder Import (b) (4)<br>(b) (4)            | 22 Nov 2020 05:42:09                         |
| Data point term sent to Coder Coding entries removed.                                                                                                                                                    | System<br>Kaitlin Mason (b) (4)<br>(b) (4) | 17 Nov 2020 20:06:40<br>17 Nov 2020 20:05:56 |
| User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4)            | 08 Oct 2020 23:21:21                         |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.                                                                                                     | Coder Import (b) (4)<br>(b) (4)            | 08 Oct 2020 23:21:21                         |
| Data point term sent to Coder Coding entries removed.                                                                                                                                                    | System<br>Kaitlin Mason (b) (4)<br>(b) (4) | 05 Oct 2020 17:52:44<br>05 Oct 2020 17:52:33 |
| User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4)            | 01 Oct 2020 20:37:00                         |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.                                                                                                     | Coder Import (b) (4)<br>(b) (4)            | 01 Oct 2020 20:37:00                         |
| Data point term sent to Coder DataPoint Verified.                                                                                                                                                        | System<br>(b) (4), (b) (6)<br>(b) (4)      | 01 Oct 2020 20:35:33<br>01 Oct 2020 20:35:28 |
| User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4)            | 26 Sep 2020 09:01:43                         |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 11:15:04**

[Name of Medication](#)

| Audit                                                                                                                                                                          | User                                                          | Time (GMT)                                                               |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------|--------------------------------------------------------------------------|
| User coded data point as Term Coded data point by<br>User: (b) (6) - version<br>WHODrug-Global-B3\\202003.<br>Data point term sent to Coder<br>User entered 'TYLENOL GEL CAPS' | Coder Import (b) (4)<br>(b) (4)<br>System<br>(b) (4), (b) (6) | 26 Sep 2020 09:01:43<br><br>25 Sep 2020 16:02:21<br>25 Sep 2020 16:01:38 |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 11:15:04**

[Prophylaxis](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 01 Oct 2020 20:35:28 |
| User entered 'No (N)' | (b) (4), (b) (6) | 25 Sep 2020 16:01:38 |

US3742169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:15:04

[Indication](#)

| Audit                                                                                                                                                                                                                                                                                             | User                  | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|----------------------|
| Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' answered with 'within time frame of RA AE' (Site from DM).       | Kaitlin Mason (b) (4) | 17 Nov 2020 20:08:59 |
| Query 'Per DM CLR: Please provide the specific location of joint pain (eg, generalized arthralgia knee joint pain, shoulder joint pain, etc.) Review and update Indication and ensure to reconcile with AE/MH entries so there is an appropriate match. ' answered with 'Updated' (Site from DM). | Kaitlin Mason (b) (4) | 17 Nov 2020 20:06:13 |
| DataPoint Un-verified.                                                                                                                                                                                                                                                                            | Kaitlin Mason (b) (4) | 17 Nov 2020 20:05:56 |
| User entered 'rheumatoid arthritis' reason for change: Data Entry Error                                                                                                                                                                                                                           | Kaitlin Mason (b) (4) | 17 Nov 2020 20:05:56 |
| User opened query 'Per DM CLR: Please provide the specific location of joint pain (eg, generalized arthralgia knee joint pain, shoulder joint pain, etc.) Review and update Indication and ensure to reconcile with AE/MH entries so there is an appropriate match. ' (Site from DM).             | (b) (4), (b) (6)      | 17 Nov 2020 07:13:24 |
| User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' (Site from DM).                                      | (b) (4), (b) (6)      | 17 Nov 2020 07:12:44 |
| DataPoint Verified.                                                                                                                                                                                                                                                                               | (b) (4), (b) (6)      | 01 Oct 2020 20:35:28 |
| User entered 'JOINT PAIN'                                                                                                                                                                                                                                                                         | (b) (4), (b) (6)      | 25 Sep 2020 16:01:38 |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 11:15:04**

[Dose per administration](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 20:35:28 |
| User entered '650'  | (b) (4), (b) (6) | 25 Sep 2020 16:01:38 |



US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 11:15:04**

[Dose unit](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 01 Oct 2020 20:35:28 |
| User entered 'mg (mg)' | (b) (4), (b) (6) | 25 Sep 2020 16:01:38 |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 11:15:04**

[If dose unit is Other, specify](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 20:35:28 |
| User entered empty. | (b) (4), (b) (6) | 25 Sep 2020 16:01:38 |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 11:15:04**

[Frequency](#)

| Audit                          | User             | Time (GMT)           |
|--------------------------------|------------------|----------------------|
| DataPoint Verified.            | (b) (4), (b) (6) | 01 Oct 2020 20:35:28 |
| User entered 'as needed (PRN)' | (b) (4), (b) (6) | 25 Sep 2020 16:01:38 |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 11:15:04**

[If frequency is Other, specify](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 20:35:28 |
| User entered empty. | (b) (4), (b) (6) | 25 Sep 2020 16:01:38 |

US3742169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:15:04

[Route of administration](#)

| Audit                                                          | User                  | Time (GMT)           |
|----------------------------------------------------------------|-----------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)      | 14 Oct 2020 20:09:02 |
| DataPoint Un-verified.                                         | Kaitlin Mason (b) (4) | 05 Oct 2020 17:52:33 |
| User entered 'Oral (ORAL)' reason for change: Data Entry Error | (b) (4)               | 05 Oct 2020 17:52:33 |
| DataPoint Verified.                                            | (b) (4), (b) (6)      | 01 Oct 2020 20:35:28 |
| User entered 'Other (OTHER)'                                   | (b) (4), (b) (6)      | 25 Sep 2020 16:01:38 |

US3742169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:15:04

If route of administration is Other, specify

| Audit                                                                                                                                                                                          | User                  | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|----------------------|
| DataPoint Verified.                                                                                                                                                                            | (b) (4), (b) (6)      | 14 Oct 2020 20:09:02 |
| User closed query 'Per CDM: Kindly provide the meaning of acronym TIB. Please enter this in "If route of administration is Other, specify" field as appropriate. ' (Site from DM).             | (b) (4), (b) (6)      | 12 Oct 2020 10:21:38 |
| Query 'Per CDM: Kindly provide the meaning of acronym TIB. Please enter this in "If route of administration is Other, specify" field as appropriate. ' answered with 'UPDATED' (Site from DM). | Kaitlin Mason (b) (4) | 05 Oct 2020 17:52:39 |
| User entered empty; reason for change Data Entry Error                                                                                                                                         | Kaitlin Mason (b) (4) | 05 Oct 2020 17:52:33 |
| DataPoint Un-verified.                                                                                                                                                                         | (b) (4), (b) (6)      | 01 Oct 2020 20:35:52 |
| DataPoint Verified.                                                                                                                                                                            | (b) (4), (b) (6)      | 01 Oct 2020 20:35:28 |
| User opened query 'Per CDM: Kindly provide the meaning of acronym TIB. Please enter this in "If route of administration is Other, specify" field as appropriate. ' (Site from DM).             | (b) (4), (b) (6)      | 01 Oct 2020 10:19:14 |
| User entered 'T.I.B'                                                                                                                                                                           | (b) (4), (b) (6)      | 25 Sep 2020 16:01:38 |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 11:15:04**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 01 Oct 2020 20:35:28 |
| User entered '16 Sep 2020' | (b) (4), (b) (6) | 25 Sep 2020 16:01:38 |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 11:15:04**

[Start date completely unknown](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 20:35:28 |
| User entered '0'    | (b) (4), (b) (6) | 25 Sep 2020 16:01:38 |



US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 11:15:04**

[Ongoing?](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 01 Oct 2020 20:35:28 |
| User entered 'No (N)' | (b) (4), (b) (6) | 25 Sep 2020 16:01:38 |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 11:15:04**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 01 Oct 2020 20:35:28 |
| User entered '24 Sep 2020' | (b) (4), (b) (6) | 25 Sep 2020 16:01:38 |

US3742169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:15:04

[Was this medication taken for solicited event?](#)

| Audit                                                                                                                                                                                                                                | User                  | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|----------------------|
| Query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol. Review and update entry as appropriate.' answered with 'updated' (Site from DM). | Kaitlin Mason (b) (4) | 17 Nov 2020 20:08:46 |
| DataPoint Un-verified.                                                                                                                                                                                                               | Kaitlin Mason (b) (4) | 17 Nov 2020 20:05:56 |
| User entered 'No (N)' reason for change: Data Entry Error                                                                                                                                                                            | Kaitlin Mason (b) (4) | 17 Nov 2020 20:05:56 |
| User opened query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol. Review and update entry as appropriate.' (Site from DM).             | (b) (4), (b) (6)      | 17 Nov 2020 07:14:19 |
| DataPoint Verified.                                                                                                                                                                                                                  | (b) (4), (b) (6)      | 01 Oct 2020 20:35:28 |
| User entered 'Yes (Y)'                                                                                                                                                                                                               | (b) (4), (b) (6)      | 25 Sep 2020 16:01:38 |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 11:15:04**

[Separate Dosage Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 25 Sep 2020 16:01:38 |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 11:15:04**

[Interval Dosage Unit Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 25 Sep 2020 16:01:38 |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 11:15:04**

[Interval Dosage Definition \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 25 Sep 2020 16:01:38 |

US3742169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:15:04

[Name of Medication](#)

| Audit                                                                                                                                                                                                                                                                                        | User                            | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------|----------------------|
| User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS, ATC: OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS, ATC: VARIOUS ALIMENTARY TRACT AND METABOLISM PRODUCTS, PRODUCT: PROBIOTICS NOS - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4) | 01 Nov 2020 03:50:49 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.                                                                                                                                                                                         | Coder Import (b) (4)<br>(b) (4) | 01 Nov 2020 03:50:49 |
| DataPoint Verified.                                                                                                                                                                                                                                                                          | (b) (4), (b) (6)                | 14 Oct 2020 20:09:02 |
| Data point term sent to Coder                                                                                                                                                                                                                                                                | System                          | 13 Oct 2020 17:03:47 |
| Data point term sent to Coder                                                                                                                                                                                                                                                                | System                          | 06 Oct 2020 14:07:08 |
| User entered 'TRUNATURE DIGESTIBE PROBIOTIC'                                                                                                                                                                                                                                                 | (b) (4), (b) (6)                | 06 Oct 2020 14:06:20 |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 11:15:04**

[Prophylaxis](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 14 Oct 2020 20:09:02 |
| User entered 'No (N)' | (b) (4), (b) (6) | 06 Oct 2020 14:06:20 |



US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 11:15:04**

[Indication](#)

| Audit                       | User             | Time (GMT)           |
|-----------------------------|------------------|----------------------|
| DataPoint Verified.         | (b) (4), (b) (6) | 14 Oct 2020 20:09:02 |
| User entered 'CONSTIPATION' | (b) (4), (b) (6) | 06 Oct 2020 14:06:20 |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 11:15:04**

[Dose per administration](#)

| Audit                                                                                  | User                    | Time (GMT)           |
|----------------------------------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                                                    | (b) (4), (b) (6)        | 14 Oct 2020 20:09:02 |
| User closed query 'Data is required. Please complete.' (Site from System).             | System                  | 13 Oct 2020 17:03:26 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System                  | 13 Oct 2020 17:03:26 |
| User entered '2' reason for change: Data Entry Error                                   | Sherry McCammon (b) (4) | 13 Oct 2020 17:03:26 |
| User opened query 'Data is required. Please complete.' (Site from System).             | System                  | 06 Oct 2020 14:06:20 |
| User entered empty.                                                                    | (b) (4), (b) (6)        | 06 Oct 2020 14:06:20 |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 11:15:04**

[Dose unit](#)

| Audit                                                                                  | User                    | Time (GMT)           |
|----------------------------------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                                                    | (b) (4), (b) (6)        | 14 Oct 2020 20:09:02 |
| User closed query 'Data is required. Please complete.' (Site from System).             | System                  | 13 Oct 2020 17:03:26 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System                  | 13 Oct 2020 17:03:26 |
| User entered 'Other (OTHER)' reason for change: Data Entry Error                       | Sherry McCammon (b) (4) | 13 Oct 2020 17:03:26 |
| User opened query 'Data is required. Please complete.' (Site from System).             | System                  | 06 Oct 2020 14:06:20 |
| User entered empty.                                                                    | (b) (4), (b) (6)        | 06 Oct 2020 14:06:20 |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 11:15:04**

[If dose unit is Other, specify](#)

| Audit                                                      | User                    | Time (GMT)           |
|------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                        | (b) (4), (b) (6)        | 14 Oct 2020 20:09:02 |
| User entered 'gummies' reason for change: Data Entry Error | Sherry McCammon (b) (4) | 13 Oct 2020 17:03:26 |
| User entered empty.                                        | (b) (4)                 |                      |
|                                                            | (b) (4), (b) (6)        | 06 Oct 2020 14:06:20 |
|                                                            |                         |                      |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 11:15:04**

[Frequency](#)

| Audit                                                                                  | User                    | Time (GMT)           |
|----------------------------------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                                                    | (b) (4), (b) (6)        | 14 Oct 2020 20:09:02 |
| User closed query 'Data is required. Please complete.' (Site from System).             | System                  | 13 Oct 2020 17:03:26 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System                  | 13 Oct 2020 17:03:26 |
| User entered 'as needed (PRN)' reason for change: Data Entry Error                     | Sherry McCammon (b) (4) | 13 Oct 2020 17:03:26 |
| User opened query 'Data is required. Please complete.' (Site from System).             | System                  | 06 Oct 2020 14:06:20 |
| User entered empty.                                                                    | (b) (4), (b) (6)        | 06 Oct 2020 14:06:20 |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 11:15:04**

[If frequency is Other, specify](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 20:09:02 |
| User entered empty. | (b) (4), (b) (6) | 06 Oct 2020 14:06:20 |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 11:15:04**

[Route of administration](#)

| Audit                                                                                  | User                    | Time (GMT)           |
|----------------------------------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                                                    | (b) (4), (b) (6)        | 14 Oct 2020 20:09:02 |
| User closed query 'Data is required. Please complete.' (Site from System).             | System                  | 13 Oct 2020 17:03:26 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System                  | 13 Oct 2020 17:03:26 |
| User entered 'Oral (ORAL)' reason for change: Data Entry Error                         | Sherry McCammon (b) (4) | 13 Oct 2020 17:03:26 |
| User opened query 'Data is required. Please complete.' (Site from System).             | System                  | 06 Oct 2020 14:06:20 |
| User entered empty.                                                                    | (b) (4), (b) (6)        | 06 Oct 2020 14:06:20 |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 11:15:04**

If route of administration is Other, specify

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 20:09:02 |
| User entered empty. | (b) (4), (b) (6) | 06 Oct 2020 14:06:20 |



US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 11:15:04**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 14 Oct 2020 20:09:02 |
| User entered '23 Sep 2020' | (b) (4), (b) (6) | 06 Oct 2020 14:06:20 |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 11:15:04**

[Start date completely unknown](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 20:09:02 |
| User entered '0'    | (b) (4), (b) (6) | 06 Oct 2020 14:06:20 |

US3742169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:15:04

[Ongoing?](#)

| Audit                                                                                                                                                                                                                                                                                                      | User                             | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------|----------------------|
| Query 'Per DM CLR: The corresponding AE has resolved, however the medication is still ongoing. Please verify and update stop date for this Con Med and/or AE as appropriate. Otherwise, provide clarification for continued use of medication.' answered with 'constipation still ongoing' (Site from DM). | Kaitlin Mason (b) (4)<br>(b) (4) | 17 Nov 2020 20:09:39 |
| User opened query 'Per DM CLR: The corresponding AE has resolved, however the medication is still ongoing. Please verify and update stop date for this Con Med and/or AE as appropriate. Otherwise, provide clarification for continued use of medication.' (Site from DM).                                | (b) (4), (b) (6)<br>(b) (4)      | 17 Nov 2020 07:11:31 |
| DataPoint Verified.                                                                                                                                                                                                                                                                                        | (b) (4), (b) (6)<br>(b) (4)      | 14 Oct 2020 20:09:02 |
| User closed query 'Data is required. Please complete.' (Site from System).                                                                                                                                                                                                                                 | System                           | 06 Oct 2020 14:07:07 |
| Query 'Data is required. Please complete.' answered by data change (Site from System).                                                                                                                                                                                                                     | System                           | 06 Oct 2020 14:07:07 |
| User entered 'Yes (Y)' reason for change: Data Entry Error                                                                                                                                                                                                                                                 | (b) (4), (b) (6)<br>(b) (4)      | 06 Oct 2020 14:07:07 |
| User opened query 'Data is required. Please complete.' (Site from System).                                                                                                                                                                                                                                 | System                           | 06 Oct 2020 14:06:20 |
| User entered empty.                                                                                                                                                                                                                                                                                        | (b) (4), (b) (6)<br>(b) (4)      | 06 Oct 2020 14:06:20 |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 11:15:04**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 20:09:02 |
| User entered empty. | (b) (4), (b) (6) | 06 Oct 2020 14:06:20 |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 11:15:04**

[Was this medication taken for solicited event?](#)

| Audit                                                                                  | User                    | Time (GMT)           |
|----------------------------------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                                                    | (b) (4), (b) (6)        | 14 Oct 2020 20:09:02 |
| User closed query 'Data is required. Please complete.' (Site from System).             | System                  | 13 Oct 2020 17:03:26 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System                  | 13 Oct 2020 17:03:26 |
| User entered 'No (N)' reason for change: Data Entry Error                              | Sherry McCammon (b) (4) | 13 Oct 2020 17:03:26 |
| User opened query 'Data is required. Please complete.' (Site from System).             | System                  | 06 Oct 2020 14:06:20 |
| User entered empty.                                                                    | (b) (4), (b) (6)        | 06 Oct 2020 14:06:20 |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 11:15:04**

[Separate Dosage Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 06 Oct 2020 14:06:20 |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 11:15:04**

[Interval Dosage Unit Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 06 Oct 2020 14:06:20 |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 11:15:04**

[Interval Dosage Definition \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 06 Oct 2020 14:06:20 |



US3742169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:15:04

[Name of Medication](#)

| Audit                                                                                                                                                                                                    | User                               | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------|----------------------|
| DataPoint Verified.                                                                                                                                                                                      | (b) (4), (b) (6)                   | 14 Oct 2020 20:09:02 |
| User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4)    | 13 Oct 2020 17:05:16 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.                                                                                                | Coder Import (b) (4)<br>(b) (4)    | 13 Oct 2020 17:05:16 |
| Data point term sent to Coder                                                                                                                                                                            | System                             | 13 Oct 2020 17:04:48 |
| User entered 'TYLENOL'                                                                                                                                                                                   | Sherry McCammon (b) (4)<br>(b) (4) | 13 Oct 2020 17:04:31 |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 11:15:04**

[Prophylaxis](#)

| Audit                 | User                    | Time (GMT)           |
|-----------------------|-------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)        | 14 Oct 2020 20:09:02 |
| User entered 'No (N)' | Sherry McCammon (b) (4) | 13 Oct 2020 17:04:31 |
|                       | (b) (4)                 |                      |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 11:15:04**

[Indication](#)

| Audit                               | User                    | Time (GMT)           |
|-------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                 | (b) (4), (b) (6)        | 14 Oct 2020 20:09:02 |
| User entered 'RHEUMATOID ARTHRITIS' | Sherry McCammon (b) (4) | 13 Oct 2020 17:04:31 |
|                                     | (b) (4)                 |                      |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 11:15:04**

[Dose per administration](#)

| Audit               | User                    | Time (GMT)           |
|---------------------|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)        | 14 Oct 2020 20:09:02 |
| User entered '1000' | Sherry McCammon (b) (4) | 13 Oct 2020 17:04:31 |
|                     | (b) (4)                 |                      |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 11:15:04**

[Dose unit](#)

| Audit                  | User                    | Time (GMT)           |
|------------------------|-------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)        | 14 Oct 2020 20:09:02 |
| User entered 'mg (mg)' | Sherry McCammon (b) (4) | 13 Oct 2020 17:04:31 |
|                        | (b) (4)                 |                      |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 11:15:04**

[If dose unit is Other, specify](#)

| Audit               | User                    | Time (GMT)           |
|---------------------|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)        | 14 Oct 2020 20:09:02 |
| User entered empty. | Sherry McCammon (b) (4) | 13 Oct 2020 17:04:31 |
|                     | (b) (4)                 |                      |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 11:15:04**

[Frequency](#)

| Audit                          | User                    | Time (GMT)           |
|--------------------------------|-------------------------|----------------------|
| DataPoint Verified.            | (b) (4), (b) (6)        | 14 Oct 2020 20:09:02 |
| User entered 'as needed (PRN)' | Sherry McCammon (b) (4) | 13 Oct 2020 17:04:31 |
|                                | (b) (4)                 |                      |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 11:15:04**

[If frequency is Other, specify](#)

| Audit               | User                    | Time (GMT)           |
|---------------------|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)        | 14 Oct 2020 20:09:02 |
| User entered empty. | Sherry McCammon (b) (4) | 13 Oct 2020 17:04:31 |
|                     | (b) (4)                 |                      |



US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 11:15:04**

[Route of administration](#)

| Audit                      | User                    | Time (GMT)           |
|----------------------------|-------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)        | 14 Oct 2020 20:09:02 |
| User entered 'Oral (ORAL)' | Sherry McCammon (b) (4) | 13 Oct 2020 17:04:31 |
|                            | (b) (4)                 |                      |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 11:15:04**

If route of administration is Other, specify

| Audit               | User                    | Time (GMT)           |
|---------------------|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)        | 14 Oct 2020 20:09:02 |
| User entered empty. | Sherry McCammon (b) (4) | 13 Oct 2020 17:04:31 |
|                     | (b) (4)                 |                      |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 11:15:04**

[Start date \(dd MMM yyyy\)](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)        | 14 Oct 2020 20:09:02 |
| User entered '9 Oct 2020' | Sherry McCammon (b) (4) | 13 Oct 2020 17:04:31 |
|                           | (b) (4)                 |                      |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 11:15:04**

[Start date completely unknown](#)

| Audit               | User                    | Time (GMT)           |
|---------------------|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)        | 14 Oct 2020 20:09:02 |
| User entered '0'    | Sherry McCammon (b) (4) | 13 Oct 2020 17:04:31 |
|                     | (b) (4)                 |                      |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 11:15:04**

[Ongoing?](#)

| Audit                  | User                    | Time (GMT)           |
|------------------------|-------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)        | 14 Oct 2020 20:09:02 |
| User entered 'Yes (Y)' | Sherry McCammon (b) (4) | 13 Oct 2020 17:04:31 |
|                        | (b) (4)                 |                      |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 11:15:04**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit               | User                    | Time (GMT)           |
|---------------------|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)        | 14 Oct 2020 20:09:02 |
| User entered empty. | Sherry McCammon (b) (4) | 13 Oct 2020 17:04:31 |
|                     | (b) (4)                 |                      |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 11:15:04**

[Was this medication taken for solicited event?](#)

| Audit                 | User                    | Time (GMT)           |
|-----------------------|-------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)        | 14 Oct 2020 20:09:02 |
| User entered 'No (N)' | Sherry McCammon (b) (4) | 13 Oct 2020 17:04:31 |
|                       | (b) (4)                 |                      |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 11:15:04**

[Separate Dosage Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 13 Oct 2020 17:04:31 |



US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 11:15:04**

[Interval Dosage Unit Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 13 Oct 2020 17:04:31 |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 11:15:04**

[Interval Dosage Definition \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 13 Oct 2020 17:04:31 |

US3742169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:15:04

[Name of Medication](#)

| Audit                                                                                                                                                                                                                                                                                      | User                               | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------|----------------------|
| User coded data point as ATC:<br>MUSCULO-SKELETAL SYSTEM, ATC:<br>ANTIINFLAMMATORY AND ANTIRHEUMATIC<br>PRODUCTS, ATC: ANTIINFLAMMATORY AND<br>ANTIRHEUMATIC PRODUCTS,<br>NON-STEROIDS, ATC: OXICAMS, PRODUCT:<br>MELOXICAM, PRODUCTSYNONYM: MOBIC -<br>version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4)    | 29 Oct 2020 17:15:33 |
| User coded data point as Term Coded data point by<br>User: (b) (6) - version<br>WHODrug-Global-B3\\202003.                                                                                                                                                                                 | Coder Import (b) (4)<br>(b) (4)    | 29 Oct 2020 17:15:33 |
| DataPoint Verified.                                                                                                                                                                                                                                                                        | (b) (4), (b) (6)                   | 28 Oct 2020 15:59:30 |
| Data point term sent to Coder                                                                                                                                                                                                                                                              | System                             | 27 Oct 2020 16:27:12 |
| User entered 'MOBIC'                                                                                                                                                                                                                                                                       | Sherry McCammon (b) (4)<br>(b) (4) | 27 Oct 2020 16:26:39 |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 11:15:04**

[Prophylaxis](#)

| Audit                 | User                    | Time (GMT)           |
|-----------------------|-------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)        | 28 Oct 2020 15:59:30 |
| User entered 'No (N)' | Sherry McCammon (b) (4) | 27 Oct 2020 16:26:39 |
|                       | (b) (4)                 |                      |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 11:15:04**

[Indication](#)

| Audit                               | User                    | Time (GMT)           |
|-------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                 | (b) (4), (b) (6)        | 28 Oct 2020 15:59:30 |
| User entered 'RHEUMATOID ARTHRITIS' | Sherry McCammon (b) (4) | 27 Oct 2020 16:26:39 |
|                                     | (b) (4)                 |                      |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 11:15:04**

[Dose per administration](#)

| Audit               | User                    | Time (GMT)           |
|---------------------|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)        | 28 Oct 2020 15:59:30 |
| User entered '7.5'  | Sherry McCammon (b) (4) | 27 Oct 2020 16:26:39 |
|                     | (b) (4)                 |                      |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 11:15:04**

[Dose unit](#)

| Audit                  | User                    | Time (GMT)           |
|------------------------|-------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)        | 28 Oct 2020 15:59:30 |
| User entered 'mg (mg)' | Sherry McCammon (b) (4) | 27 Oct 2020 16:26:39 |
|                        | (b) (4)                 |                      |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 11:15:04**

[If dose unit is Other, specify](#)

| Audit               | User                    | Time (GMT)           |
|---------------------|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)        | 28 Oct 2020 15:59:30 |
| User entered empty. | Sherry McCammon (b) (4) | 27 Oct 2020 16:26:39 |
|                     | (b) (4)                 |                      |



US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 11:15:04**

[Frequency](#)

| Audit                          | User                    | Time (GMT)           |
|--------------------------------|-------------------------|----------------------|
| DataPoint Verified.            | (b) (4), (b) (6)        | 28 Oct 2020 15:59:30 |
| User entered 'as needed (PRN)' | Sherry McCammon (b) (4) | 27 Oct 2020 16:26:39 |
|                                | (b) (4)                 |                      |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 11:15:04**

[If frequency is Other, specify](#)

| Audit               | User                    | Time (GMT)           |
|---------------------|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)        | 28 Oct 2020 15:59:30 |
| User entered empty. | Sherry McCammon (b) (4) | 27 Oct 2020 16:26:39 |
|                     | (b) (4)                 |                      |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 11:15:04**

[Route of administration](#)

| Audit                      | User                    | Time (GMT)           |
|----------------------------|-------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)        | 28 Oct 2020 15:59:30 |
| User entered 'Oral (ORAL)' | Sherry McCammon (b) (4) | 27 Oct 2020 16:26:39 |
|                            | (b) (4)                 |                      |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 11:15:04**

If route of administration is Other, specify

| Audit               | User                    | Time (GMT)           |
|---------------------|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)        | 28 Oct 2020 15:59:30 |
| User entered empty. | Sherry McCammon (b) (4) | 27 Oct 2020 16:26:39 |
|                     | (b) (4)                 |                      |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 11:15:04**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                    | Time (GMT)           |
|----------------------------|-------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)        | 28 Oct 2020 15:59:30 |
| User entered '20 Oct 2020' | Sherry McCammon (b) (4) | 27 Oct 2020 16:26:39 |
|                            | (b) (4)                 |                      |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 11:15:04**

[Start date completely unknown](#)

| Audit               | User                    | Time (GMT)           |
|---------------------|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)        | 28 Oct 2020 15:59:30 |
| User entered '0'    | Sherry McCammon (b) (4) | 27 Oct 2020 16:26:39 |
|                     | (b) (4)                 |                      |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 11:15:04**

[Ongoing?](#)

| Audit                  | User                    | Time (GMT)           |
|------------------------|-------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)        | 28 Oct 2020 15:59:30 |
| User entered 'Yes (Y)' | Sherry McCammon (b) (4) | 27 Oct 2020 16:26:39 |
|                        | (b) (4)                 |                      |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 11:15:04**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit               | User                    | Time (GMT)           |
|---------------------|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)        | 28 Oct 2020 15:59:30 |
| User entered empty. | Sherry McCammon (b) (4) | 27 Oct 2020 16:26:39 |
|                     | (b) (4)                 |                      |



US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 11:15:04**

[Was this medication taken for solicited event?](#)

| Audit                 | User                    | Time (GMT)           |
|-----------------------|-------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)        | 28 Oct 2020 15:59:30 |
| User entered 'No (N)' | Sherry McCammon (b) (4) | 27 Oct 2020 16:26:39 |
|                       | (b) (4)                 |                      |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 11:15:04**

[Separate Dosage Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 27 Oct 2020 16:26:39 |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 11:15:04**

[Interval Dosage Unit Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 27 Oct 2020 16:26:39 |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 11:15:04**

[Interval Dosage Definition \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 27 Oct 2020 16:26:39 |

US3742169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:15:04

[Name of Medication](#)

| Audit                                                                                                                                                                                       | User                               | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------|----------------------|
| User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4)    | 19 Nov 2020 22:58:51 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.                                                                                        | Coder Import (b) (4)<br>(b) (4)    | 19 Nov 2020 22:58:51 |
| Data point term sent to Coder                                                                                                                                                               | System                             | 19 Nov 2020 20:30:38 |
| User entered 'FLU VACCINE'                                                                                                                                                                  | Sherry McCammon (b) (4)<br>(b) (4) | 19 Nov 2020 20:30:28 |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 26 Nov 2020 11:15:04**

[Prophylaxis](#)

| Audit                  | User                    | Time (GMT)           |
|------------------------|-------------------------|----------------------|
| User entered 'Yes (Y)' | Sherry McCammon (b) (4) | 19 Nov 2020 20:30:28 |
|                        | (b) (4)                 |                      |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 26 Nov 2020 11:15:04**

[Indication](#)

| Audit                                    | User                    | Time (GMT)           |
|------------------------------------------|-------------------------|----------------------|
| User entered 'VIRAL ILLNESS UNSPECIFIED' | Sherry McCammon (b) (4) | 19 Nov 2020 20:30:28 |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 26 Nov 2020 11:15:04**

[Dose per administration](#)

| Audit              | User                    | Time (GMT)           |
|--------------------|-------------------------|----------------------|
| User entered '0.5' | Sherry McCammon (b) (4) | 19 Nov 2020 20:30:28 |
|                    | (b) (4)                 |                      |



US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 26 Nov 2020 11:15:04**

[Dose unit](#)

| Audit                  | User                    | Time (GMT)           |
|------------------------|-------------------------|----------------------|
| User entered 'mL (mL)' | Sherry McCammon (b) (4) | 19 Nov 2020 20:30:28 |
|                        | (b) (4)                 |                      |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 26 Nov 2020 11:15:04**

If dose unit is Other, specify

| Audit               | User                    | Time (GMT)           |
|---------------------|-------------------------|----------------------|
| User entered empty. | Sherry McCammon (b) (4) | 19 Nov 2020 20:30:28 |
|                     | (b) (4)                 |                      |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 26 Nov 2020 11:15:04**

[Frequency](#)

| Audit                      | User                    | Time (GMT)           |
|----------------------------|-------------------------|----------------------|
| User entered 'once (ONCE)' | Sherry McCammon (b) (4) | 19 Nov 2020 20:30:28 |
|                            | (b) (4)                 |                      |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 26 Nov 2020 11:15:04**

[If frequency is Other, specify](#)

| Audit               | User                    | Time (GMT)           |
|---------------------|-------------------------|----------------------|
| User entered empty. | Sherry McCammon (b) (4) | 19 Nov 2020 20:30:28 |
|                     | (b) (4)                 |                      |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 26 Nov 2020 11:15:04**

[Route of administration](#)

| Audit                                        | User                    | Time (GMT)           |
|----------------------------------------------|-------------------------|----------------------|
| User entered 'Intramuscular (INTRAMUSCULAR)' | Sherry McCammon (b) (4) | 19 Nov 2020 20:30:28 |
|                                              | (b) (4)                 |                      |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 26 Nov 2020 11:15:04**

If route of administration is Other, specify

| Audit               | User                    | Time (GMT)           |
|---------------------|-------------------------|----------------------|
| User entered empty. | Sherry McCammon (b) (4) | 19 Nov 2020 20:30:28 |
|                     | (b) (4)                 |                      |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 26 Nov 2020 11:15:04**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                    | Time (GMT)           |
|----------------------------|-------------------------|----------------------|
| User entered '02 Nov 2020' | Sherry McCammon (b) (4) | 19 Nov 2020 20:30:28 |
|                            | (b) (4)                 |                      |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 26 Nov 2020 11:15:04**

[Start date completely unknown](#)

| Audit            | User                    | Time (GMT)           |
|------------------|-------------------------|----------------------|
| User entered '0' | Sherry McCammon (b) (4) | 19 Nov 2020 20:30:28 |
|                  | (b) (4)                 |                      |



US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 26 Nov 2020 11:15:04**

[Ongoing?](#)

| Audit                 | User                    | Time (GMT)           |
|-----------------------|-------------------------|----------------------|
| User entered 'No (N)' | Sherry McCammon (b) (4) | 19 Nov 2020 20:30:28 |
|                       | (b) (4)                 |                      |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 26 Nov 2020 11:15:04**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit                      | User                    | Time (GMT)           |
|----------------------------|-------------------------|----------------------|
| User entered '02 Nov 2020' | Sherry McCammon (b) (4) | 19 Nov 2020 20:30:28 |
|                            | (b) (4)                 |                      |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 26 Nov 2020 11:15:04**

[Was this medication taken for solicited event?](#)

| Audit                 | User                    | Time (GMT)           |
|-----------------------|-------------------------|----------------------|
| User entered 'No (N)' | Sherry McCammon (b) (4) | 19 Nov 2020 20:30:28 |
|                       | (b) (4)                 |                      |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 26 Nov 2020 11:15:04**

[Separate Dosage Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 19 Nov 2020 20:30:28 |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 26 Nov 2020 11:15:04**

[Interval Dosage Unit Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 19 Nov 2020 20:30:28 |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 26 Nov 2020 11:15:04**

[Interval Dosage Definition \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 19 Nov 2020 20:30:28 |

US3742169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:15:04

[Name of Medication](#)

| Audit                                                                                                                                                                                                                                                          | User                    | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|----------------------|
| User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: PIPERAZINE DERIVATIVES, PRODUCT: LEVOCETIRIZINE DIHYDROCHLORIDE, PRODUCTSYNONYM: XYZAL - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)    | 19 Nov 2020 20:42:05 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.                                                                                                                                                      | Coder Import (b) (4)    | 19 Nov 2020 20:42:05 |
| Data point term sent to Coder                                                                                                                                                                                                                                  | System                  | 19 Nov 2020 20:40:58 |
| User entered 'XYZAL'                                                                                                                                                                                                                                           | Sherry McCammon (b) (4) | 19 Nov 2020 20:40:12 |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 26 Nov 2020 11:15:04**

[Prophylaxis](#)

| Audit                                                                                  | User                    | Time (GMT)           |
|----------------------------------------------------------------------------------------|-------------------------|----------------------|
| User closed query 'Data is required. Please complete.' (Site from System).             | System                  | 19 Nov 2020 20:42:46 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System                  | 19 Nov 2020 20:42:46 |
| User entered 'No (N)' reason for change: Data Entry Error                              | Sherry McCammon (b) (4) | 19 Nov 2020 20:42:46 |
| User opened query 'Data is required. Please complete.' (Site from System).             | System                  | 19 Nov 2020 20:40:12 |
| User entered empty.                                                                    | Sherry McCammon (b) (4) | 19 Nov 2020 20:40:12 |



US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 26 Nov 2020 11:15:04**

[Indication](#)

| Audit                                    | User                    | Time (GMT)           |
|------------------------------------------|-------------------------|----------------------|
| User entered 'VIRAL ILLNESS UNSPECIFIED' | Sherry McCammon (b) (4) | 19 Nov 2020 20:40:12 |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 26 Nov 2020 11:15:04**

[Dose per administration](#)

| Audit               | User                    | Time (GMT)           |
|---------------------|-------------------------|----------------------|
| User entered '3.75' | Sherry McCammon (b) (4) | 19 Nov 2020 20:40:12 |
|                     | (b) (4)                 |                      |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 26 Nov 2020 11:15:04**

[Dose unit](#)

| Audit                  | User                    | Time (GMT)           |
|------------------------|-------------------------|----------------------|
| User entered 'mg (mg)' | Sherry McCammon (b) (4) | 19 Nov 2020 20:40:12 |
|                        | (b) (4)                 |                      |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 26 Nov 2020 11:15:04**

If dose unit is Other, specify

| Audit               | User                    | Time (GMT)           |
|---------------------|-------------------------|----------------------|
| User entered empty. | Sherry McCammon (b) (4) | 19 Nov 2020 20:40:12 |
|                     | (b) (4)                 |                      |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 26 Nov 2020 11:15:04**

[Frequency](#)

| Audit                          | User                    | Time (GMT)           |
|--------------------------------|-------------------------|----------------------|
| User entered 'as needed (PRN)' | Sherry McCammon (b) (4) | 19 Nov 2020 20:40:12 |
|                                | (b) (4)                 |                      |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 26 Nov 2020 11:15:04**

[If frequency is Other, specify](#)

| Audit               | User                    | Time (GMT)           |
|---------------------|-------------------------|----------------------|
| User entered empty. | Sherry McCammon (b) (4) | 19 Nov 2020 20:40:12 |
|                     | (b) (4)                 |                      |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 26 Nov 2020 11:15:04**

[Route of administration](#)

| Audit                      | User                    | Time (GMT)           |
|----------------------------|-------------------------|----------------------|
| User entered 'Oral (ORAL)' | Sherry McCammon (b) (4) | 19 Nov 2020 20:40:12 |
|                            | (b) (4)                 |                      |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 26 Nov 2020 11:15:04**

If route of administration is Other, specify

| Audit               | User                    | Time (GMT)           |
|---------------------|-------------------------|----------------------|
| User entered empty. | Sherry McCammon (b) (4) | 19 Nov 2020 20:40:12 |
|                     | (b) (4)                 |                      |



US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 26 Nov 2020 11:15:04**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                    | Time (GMT)           |
|----------------------------|-------------------------|----------------------|
| User entered '31 Oct 2020' | Sherry McCammon (b) (4) | 19 Nov 2020 20:40:12 |
|                            | (b) (4)                 |                      |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 26 Nov 2020 11:15:04**

[Start date completely unknown](#)

| Audit            | User                    | Time (GMT)           |
|------------------|-------------------------|----------------------|
| User entered '0' | Sherry McCammon (b) (4) | 19 Nov 2020 20:40:12 |
|                  | (b) (4)                 |                      |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 26 Nov 2020 11:15:04**

[Ongoing?](#)

| Audit                 | User                    | Time (GMT)           |
|-----------------------|-------------------------|----------------------|
| User entered 'No (N)' | Sherry McCammon (b) (4) | 19 Nov 2020 20:40:12 |
|                       | (b) (4)                 |                      |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 26 Nov 2020 11:15:04**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit                      | User                    | Time (GMT)           |
|----------------------------|-------------------------|----------------------|
| User entered '14 Nov 2020' | Sherry McCammon (b) (4) | 19 Nov 2020 20:40:12 |
|                            | (b) (4)                 |                      |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 26 Nov 2020 11:15:04**

[Was this medication taken for solicited event?](#)

| Audit                 | User                    | Time (GMT)           |
|-----------------------|-------------------------|----------------------|
| User entered 'No (N)' | Sherry McCammon (b) (4) | 19 Nov 2020 20:40:12 |
|                       | (b) (4)                 |                      |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 26 Nov 2020 11:15:04**

[Separate Dosage Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 19 Nov 2020 20:40:12 |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 26 Nov 2020 11:15:04**

[Interval Dosage Unit Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 19 Nov 2020 20:40:12 |

US3742169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 26 Nov 2020 11:15:04**

[Interval Dosage Definition \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 19 Nov 2020 20:40:12 |



US3742169

**Folder: End of Study (1)**

**Form: Dosing Discontinuation**

**Generated On: 26 Nov 2020 11:15:04**

[Date of dosing discontinuation \(dd MMM yyyy\)](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)        | 28 Oct 2020 15:59:46 |
| User entered '3 Oct 2020' | Sherry McCammon (b) (4) | 13 Oct 2020 17:09:59 |
|                           | (b) (4)                 |                      |

US3742169

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 11:15:04

[Primary reason for dosing discontinuation](#)

| Audit                                                                                                                                                           | User                    | Time (GMT)           |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|----------------------|
| User closed query 'Per CDM: there si an SAE that is recorded as IP Withdrawn. Please consider updating this field to SAE (Specify)' (Site from DM).             | (b) (4), (b) (6)        | 24 Nov 2020 18:01:21 |
| Query 'Per CDM: there si an SAE that is recorded as IP Withdrawn. Please consider updating this field to SAE (Specify)' answered with 'updated' (Site from DM). | Kaitlin Mason (b) (4)   | 24 Nov 2020 17:15:29 |
| DataPoint Un-verified.                                                                                                                                          | Kaitlin Mason (b) (4)   | 24 Nov 2020 17:13:59 |
| User entered 'SAE (specify) (SAE)' reason for change: Data Entry Error                                                                                          | Kaitlin Mason (b) (4)   | 24 Nov 2020 17:13:59 |
| User opened query 'Per CDM: there si an SAE that is recorded as IP Withdrawn. Please consider updating this field to SAE (Specify)' (Site from DM).             | (b) (4), (b) (6)        | 22 Nov 2020 23:50:54 |
| DataPoint Verified.                                                                                                                                             | (b) (4), (b) (6)        | 28 Oct 2020 15:59:46 |
| User entered 'AE (specify) (ADVERSE EVENT)'                                                                                                                     | Sherry McCammon (b) (4) | 13 Oct 2020 17:09:59 |

US3742169

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 11:15:04

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

| Audit                                                                                                                                                                    | User                    | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|----------------------|
| User closed query 'Per CDM: since IP was discontinued to as SAE please recorded the SAE record number (i.e. SAE #1 referencing log line # )' (Site from DM).             | (b) (4), (b) (6)        | 24 Nov 2020 18:01:23 |
| Query 'Per CDM: since IP was discontinued to as SAE please recorded the SAE record number (i.e. SAE #1 referencing log line # )' answered with 'updated' (Site from DM). | Kaitlin Mason (b) (4)   | 24 Nov 2020 17:16:23 |
| User entered 'SAE (AE#2)' reason for change: Data Entry Error                                                                                                            | (b) (4)                 | 24 Nov 2020 17:16:18 |
| User entered 'SAE USA-US127-2020-MRNA-1273-P301000003' reason for change: Data Entry Error                                                                               | Kaitlin Mason (b) (4)   | 24 Nov 2020 17:14:52 |
| User entered 'SAE' reason for change: Data Entry Error                                                                                                                   | Kaitlin Mason (b) (4)   | 24 Nov 2020 17:13:59 |
| User opened query 'Per CDM: since IP was discontinued to as SAE please recorded the SAE record number (i.e. SAE #1 referencing log line # )' (Site from DM).             | (b) (4), (b) (6)        | 22 Nov 2020 23:54:00 |
| User closed query 'Per CDM: Please record AE record number instead of details ' (Site from DM).                                                                          | (b) (4), (b) (6)        | 22 Nov 2020 23:49:34 |
| Query 'Per CDM: Please record AE record number instead of details ' answered with 'updated' (Site from DM).                                                              | Kaitlin Mason (b) (4)   | 19 Nov 2020 15:27:17 |
| DataPoint Un-verified.                                                                                                                                                   | Kaitlin Mason (b) (4)   | 19 Nov 2020 15:27:12 |
| User entered 'AE 2' reason for change: Data Entry Error                                                                                                                  | Kaitlin Mason (b) (4)   | 19 Nov 2020 15:27:12 |
| User opened query 'Per CDM: Please record AE record number instead of details ' (Site from DM).                                                                          | (b) (4), (b) (6)        | 18 Nov 2020 16:47:10 |
| DataPoint Verified.                                                                                                                                                      | (b) (4), (b) (6)        | 28 Oct 2020 15:59:46 |
| User entered 'RHEUMATOID ARTHRITIS'                                                                                                                                      | Sherry McCammon (b) (4) | 13 Oct 2020 17:09:59 |

US3742169

Folder: SAE USA-US127-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:04

[SAEID](#)

| Audit                                                 | User             | Time (GMT)           |
|-------------------------------------------------------|------------------|----------------------|
| DataPoint Verified.                                   | (b) (4), (b) (6) | 14 Oct 2020 20:04:55 |
| Reviewed for Safety.                                  | (b) (4), (b) (6) | 05 Oct 2020 13:32:36 |
| User entered<br>'USA-US127-2020-MRNA-1273-P301000003' | System           | 05 Oct 2020 13:32:04 |

US3742169

Folder: SAE USA-US127-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:04

Serious

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 14 Oct 2020 20:04:55 |
| Reviewed for Safety.   | (b) (4), (b) (6) | 05 Oct 2020 13:32:36 |
| User entered 'Yes (Y)' | System           | 05 Oct 2020 13:32:04 |

US3742169

Folder: SAE USA-US127-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:04

[Death](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 14 Oct 2020 20:04:55 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 05 Oct 2020 13:32:36 |
| User entered 'No (N)' | System           | 05 Oct 2020 13:32:04 |

US3742169

Folder: SAE USA-US127-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:04

[Life threatening](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 14 Oct 2020 20:04:55 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 05 Oct 2020 13:32:36 |
| User entered 'No (N)' | System           | 05 Oct 2020 13:32:04 |

US3742169

Folder: SAE USA-US127-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:04

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 14 Oct 2020 20:04:55 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 05 Oct 2020 13:32:36 |
| User entered 'No (N)' | System           | 05 Oct 2020 13:32:04 |



US3742169

Folder: SAE USA-US127-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:04

[Persistent or significant disability or incapacity](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 14 Oct 2020 20:04:55 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 05 Oct 2020 13:32:36 |
| User entered 'No (N)' | System           | 05 Oct 2020 13:32:04 |

US3742169

Folder: SAE USA-US127-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:04

[Congenital anomaly or birth defect](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 14 Oct 2020 20:04:55 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 05 Oct 2020 13:32:36 |
| User entered 'No (N)' | System           | 05 Oct 2020 13:32:04 |

US3742169

Folder: SAE USA-US127-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:04

[Other medically important event](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 14 Oct 2020 20:04:55 |
| Reviewed for Safety.   | (b) (4), (b) (6) | 05 Oct 2020 13:32:36 |
| User entered 'Yes (Y)' | System           | 05 Oct 2020 13:32:04 |

US3742169

Folder: SAE USA-US127-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:04

[Investigator's First Name](#)

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| DataPoint Verified.  | (b) (4), (b) (6) | 14 Oct 2020 20:04:55 |
| Reviewed for Safety. | (b) (4), (b) (6) | 05 Oct 2020 13:32:36 |
| User entered 'Karen' | System           | 05 Oct 2020 13:32:04 |

US3742169

Folder: SAE USA-US127-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:04

[Investigator's Last Name](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 14 Oct 2020 20:04:55 |
| Reviewed for Safety.   | (b) (4), (b) (6) | 05 Oct 2020 13:32:36 |
| User entered 'Kotloff' | System           | 05 Oct 2020 13:32:04 |

US3742169

Folder: SAE USA-US127-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:04

Site Address: [Street](#)

| Audit                                           | User             | Time (GMT)           |
|-------------------------------------------------|------------------|----------------------|
| DataPoint Verified.                             | (b) (4), (b) (6) | 14 Oct 2020 20:04:55 |
| Reviewed for Safety.                            | (b) (4), (b) (6) | 05 Oct 2020 13:32:36 |
| User entered '685 W. Baltimore Street, HSF 480' | System           | 05 Oct 2020 13:32:04 |

**US3742169**

**Folder: SAE USA-US127-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 11:15:04**

[Site Address: City](#)

| Audit                    | User             | Time (GMT)           |
|--------------------------|------------------|----------------------|
| DataPoint Verified.      | (b) (4), (b) (6) | 14 Oct 2020 20:04:55 |
| Reviewed for Safety.     | (b) (4), (b) (6) | 05 Oct 2020 13:32:36 |
| User entered 'Baltimore' | System           | 05 Oct 2020 13:32:04 |

**US3742169**

**Folder: SAE USA-US127-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 11:15:04**

[Site Address: Postal Code](#)

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| DataPoint Verified.  | (b) (4), (b) (6) | 14 Oct 2020 20:04:55 |
| Reviewed for Safety. | (b) (4), (b) (6) | 05 Oct 2020 13:32:36 |
| User entered '21201' | System           | 05 Oct 2020 13:32:04 |



US3742169

Folder: SAE USA-US127-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:04

[Investigator Country](#)

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 15 Oct 2020 12:41:34 |
|                      |                  |                      |
| DataPoint Verified.  | (b) (4), (b) (6) | 14 Oct 2020 20:04:55 |
| User entered 'US'    | System           | 05 Oct 2020 13:32:44 |

US3742169

**Folder:** SAE USA-US127-2020-MRNA-1273-P301000003

**Form:** Safety Report Form

**Generated On:** 26 Nov 2020 11:15:04

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '5' | System | 24 Nov 2020 13:31:42 |
| User entered '4' | System | 10 Nov 2020 14:11:30 |
| User entered '3' | System | 16 Oct 2020 00:38:54 |
| User entered '2' | System | 15 Oct 2020 12:41:42 |
| User entered '1' | System | 05 Oct 2020 13:32:44 |

US3742169

Folder: SAE USA-US127-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:04

[SAEID](#)

| Audit                                                 | User             | Time (GMT)           |
|-------------------------------------------------------|------------------|----------------------|
| DataPoint Verified.                                   | (b) (4), (b) (6) | 14 Oct 2020 20:04:55 |
| Reviewed for Safety.                                  | (b) (4), (b) (6) | 05 Oct 2020 13:32:36 |
| User entered<br>'USA-US127-2020-MRNA-1273-P301000003' | System           | 05 Oct 2020 13:32:04 |

US3742169

Folder: SAE USA-US127-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:04

Serious

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 14 Oct 2020 20:04:55 |
| Reviewed for Safety.   | (b) (4), (b) (6) | 05 Oct 2020 13:32:36 |
| User entered 'Yes (Y)' | System           | 05 Oct 2020 13:32:04 |

US3742169

Folder: SAE USA-US127-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:04

[Death](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 14 Oct 2020 20:04:55 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 05 Oct 2020 13:32:36 |
| User entered 'No (N)' | System           | 05 Oct 2020 13:32:04 |

US3742169

Folder: SAE USA-US127-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:04

[Life threatening](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 14 Oct 2020 20:04:55 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 05 Oct 2020 13:32:36 |
| User entered 'No (N)' | System           | 05 Oct 2020 13:32:04 |

US3742169

Folder: SAE USA-US127-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:04

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 14 Oct 2020 20:04:55 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 05 Oct 2020 13:32:36 |
| User entered 'No (N)' | System           | 05 Oct 2020 13:32:04 |

US3742169

Folder: SAE USA-US127-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:04

[Persistent or significant disability or incapacity](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 14 Oct 2020 20:04:55 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 05 Oct 2020 13:32:36 |
| User entered 'No (N)' | System           | 05 Oct 2020 13:32:04 |



US3742169

Folder: SAE USA-US127-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:04

[Congenital anomaly or birth defect](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 14 Oct 2020 20:04:55 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 05 Oct 2020 13:32:36 |
| User entered 'No (N)' | System           | 05 Oct 2020 13:32:04 |

US3742169

Folder: SAE USA-US127-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:04

[Other medically important event](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 14 Oct 2020 20:04:55 |
| Reviewed for Safety.   | (b) (4), (b) (6) | 05 Oct 2020 13:32:36 |
| User entered 'Yes (Y)' | System           | 05 Oct 2020 13:32:04 |

US3742169

Folder: SAE USA-US127-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:04

[Investigator's First Name](#)

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| DataPoint Verified.  | (b) (4), (b) (6) | 14 Oct 2020 20:04:55 |
| Reviewed for Safety. | (b) (4), (b) (6) | 05 Oct 2020 13:32:36 |
| User entered 'Karen' | System           | 05 Oct 2020 13:32:04 |

US3742169

Folder: SAE USA-US127-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:04

[Investigator's Last Name](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 14 Oct 2020 20:04:55 |
| Reviewed for Safety.   | (b) (4), (b) (6) | 05 Oct 2020 13:32:36 |
| User entered 'Kotloff' | System           | 05 Oct 2020 13:32:04 |

US3742169

Folder: SAE USA-US127-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:04

Site Address: [Street](#)

| Audit                                           | User             | Time (GMT)           |
|-------------------------------------------------|------------------|----------------------|
| DataPoint Verified.                             | (b) (4), (b) (6) | 14 Oct 2020 20:04:55 |
| Reviewed for Safety.                            | (b) (4), (b) (6) | 05 Oct 2020 13:32:36 |
| User entered '685 W. Baltimore Street, HSF 480' | System           | 05 Oct 2020 13:32:04 |

US3742169

Folder: SAE USA-US127-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:04

Site Address: [City](#)

| Audit                    | User             | Time (GMT)           |
|--------------------------|------------------|----------------------|
| DataPoint Verified.      | (b) (4), (b) (6) | 14 Oct 2020 20:04:55 |
| Reviewed for Safety.     | (b) (4), (b) (6) | 05 Oct 2020 13:32:36 |
| User entered 'Baltimore' | System           | 05 Oct 2020 13:32:04 |

US3742169

Folder: SAE USA-US127-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:04

Site Address: [Postal Code](#)

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| DataPoint Verified.  | (b) (4), (b) (6) | 14 Oct 2020 20:04:55 |
| Reviewed for Safety. | (b) (4), (b) (6) | 05 Oct 2020 13:32:36 |
| User entered '21201' | System           | 05 Oct 2020 13:32:04 |

US3742169

Folder: SAE USA-US127-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:04

[Investigator Country](#)

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 15 Oct 2020 12:41:34 |
|                      |                  |                      |
| DataPoint Verified.  | (b) (4), (b) (6) | 14 Oct 2020 20:04:55 |
| User entered 'US'    | System           | 05 Oct 2020 13:32:44 |



US3742169

**Folder:** SAE USA-US127-2020-MRNA-1273-P301000003

**Form:** Safety Report Form

**Generated On:** 26 Nov 2020 11:15:04

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '5' | System | 24 Nov 2020 13:31:42 |
| User entered '4' | System | 10 Nov 2020 14:11:30 |
| User entered '3' | System | 16 Oct 2020 00:38:54 |
| User entered '2' | System | 15 Oct 2020 12:41:42 |
| User entered '1' | System | 05 Oct 2020 13:32:44 |

US3742169

Folder: SAE USA-US127-2020-MRNA-1273-P301000003

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 11:15:04

[Date of submission \(Pre-filled from custom function\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| DataPoint Verified.              | (b) (4), (b) (6) | 14 Oct 2020 20:04:55 |
| User entered '05/Oct/2020 13:32' | System           | 05 Oct 2020 13:32:44 |

US3742169

Folder: SAE USA-US127-2020-MRNA-1273-P301000003

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 11:15:04

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 15 Oct 2020 12:41:34 |
|                      |                  |                      |
| DataPoint Verified.  | (b) (4), (b) (6) | 14 Oct 2020 20:04:55 |
|                      |                  |                      |
| User entered '1'     | (b) (4), (b) (6) | 05 Oct 2020 13:32:44 |
|                      |                  |                      |

US3742169

Folder: SAE USA-US127-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:04

[SAEID](#)

| Audit                                                 | User             | Time (GMT)           |
|-------------------------------------------------------|------------------|----------------------|
| DataPoint Verified.                                   | (b) (4), (b) (6) | 14 Oct 2020 20:04:55 |
| Reviewed for Safety.                                  | (b) (4), (b) (6) | 05 Oct 2020 13:32:36 |
| User entered<br>'USA-US127-2020-MRNA-1273-P301000003' | System           | 05 Oct 2020 13:32:04 |

US3742169

Folder: SAE USA-US127-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:04

Serious

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 14 Oct 2020 20:04:55 |
| Reviewed for Safety.   | (b) (4), (b) (6) | 05 Oct 2020 13:32:36 |
| User entered 'Yes (Y)' | System           | 05 Oct 2020 13:32:04 |

US3742169

Folder: SAE USA-US127-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:04

[Death](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 14 Oct 2020 20:04:55 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 05 Oct 2020 13:32:36 |
| User entered 'No (N)' | System           | 05 Oct 2020 13:32:04 |

US3742169

Folder: SAE USA-US127-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:04

[Life threatening](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 14 Oct 2020 20:04:55 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 05 Oct 2020 13:32:36 |
| User entered 'No (N)' | System           | 05 Oct 2020 13:32:04 |

US3742169

Folder: SAE USA-US127-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:04

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 14 Oct 2020 20:04:55 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 05 Oct 2020 13:32:36 |
| User entered 'No (N)' | System           | 05 Oct 2020 13:32:04 |



US3742169

Folder: SAE USA-US127-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:04

[Persistent or significant disability or incapacity](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 14 Oct 2020 20:04:55 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 05 Oct 2020 13:32:36 |
| User entered 'No (N)' | System           | 05 Oct 2020 13:32:04 |

US3742169

Folder: SAE USA-US127-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:04

[Congenital anomaly or birth defect](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 14 Oct 2020 20:04:55 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 05 Oct 2020 13:32:36 |
| User entered 'No (N)' | System           | 05 Oct 2020 13:32:04 |

US3742169

Folder: SAE USA-US127-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:04

[Other medically important event](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 14 Oct 2020 20:04:55 |
| Reviewed for Safety.   | (b) (4), (b) (6) | 05 Oct 2020 13:32:36 |
| User entered 'Yes (Y)' | System           | 05 Oct 2020 13:32:04 |

US3742169

Folder: SAE USA-US127-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:04

[Investigator's First Name](#)

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| DataPoint Verified.  | (b) (4), (b) (6) | 14 Oct 2020 20:04:55 |
| Reviewed for Safety. | (b) (4), (b) (6) | 05 Oct 2020 13:32:36 |
| User entered 'Karen' | System           | 05 Oct 2020 13:32:04 |

US3742169

Folder: SAE USA-US127-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:04

[Investigator's Last Name](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 14 Oct 2020 20:04:55 |
| Reviewed for Safety.   | (b) (4), (b) (6) | 05 Oct 2020 13:32:36 |
| User entered 'Kotloff' | System           | 05 Oct 2020 13:32:04 |

US3742169

Folder: SAE USA-US127-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:04

Site Address: [Street](#)

| Audit                                           | User             | Time (GMT)           |
|-------------------------------------------------|------------------|----------------------|
| DataPoint Verified.                             | (b) (4), (b) (6) | 14 Oct 2020 20:04:55 |
| Reviewed for Safety.                            | (b) (4), (b) (6) | 05 Oct 2020 13:32:36 |
| User entered '685 W. Baltimore Street, HSF 480' | System           | 05 Oct 2020 13:32:04 |

US3742169

Folder: SAE USA-US127-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:04

Site Address: [City](#)

| Audit                    | User             | Time (GMT)           |
|--------------------------|------------------|----------------------|
| DataPoint Verified.      | (b) (4), (b) (6) | 14 Oct 2020 20:04:55 |
| Reviewed for Safety.     | (b) (4), (b) (6) | 05 Oct 2020 13:32:36 |
| User entered 'Baltimore' | System           | 05 Oct 2020 13:32:04 |

US3742169

Folder: SAE USA-US127-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:04

Site Address: [Postal Code](#)

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| DataPoint Verified.  | (b) (4), (b) (6) | 14 Oct 2020 20:04:55 |
| Reviewed for Safety. | (b) (4), (b) (6) | 05 Oct 2020 13:32:36 |
| User entered '21201' | System           | 05 Oct 2020 13:32:04 |



US3742169

Folder: SAE USA-US127-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:04

[Investigator Country](#)

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 15 Oct 2020 12:41:34 |
|                      |                  |                      |
| DataPoint Verified.  | (b) (4), (b) (6) | 14 Oct 2020 20:04:55 |
| User entered 'US'    | System           | 05 Oct 2020 13:32:44 |

US3742169

Folder: SAE USA-US127-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:04

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '5' | System | 24 Nov 2020 13:31:42 |
| User entered '4' | System | 10 Nov 2020 14:11:30 |
| User entered '3' | System | 16 Oct 2020 00:38:54 |
| User entered '2' | System | 15 Oct 2020 12:41:42 |
| User entered '1' | System | 05 Oct 2020 13:32:44 |

**US3742169**

**Folder: SAE USA-US127-2020-MRNA-1273-P301000003**

**Form: Safety Report Form (2)**

**Generated On: 26 Nov 2020 11:15:04**

[Date of submission \(Pre-filled from custom function\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| DataPoint Verified.              | (b) (4), (b) (6) | 28 Oct 2020 16:00:05 |
| User entered '15/Oct/2020 08:41' | System           | 15 Oct 2020 12:41:42 |

US3742169

Folder: SAE USA-US127-2020-MRNA-1273-P301000003

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 11:15:04

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| DataPoint Verified.  | (b) (4), (b) (6) | 28 Oct 2020 16:00:05 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Oct 2020 00:38:46 |
| User entered '1'     | (b) (4), (b) (6) | 15 Oct 2020 12:41:42 |

US3742169

Folder: SAE USA-US127-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:04

[SAEID](#)

| Audit                                                 | User             | Time (GMT)           |
|-------------------------------------------------------|------------------|----------------------|
| DataPoint Verified.                                   | (b) (4), (b) (6) | 14 Oct 2020 20:04:55 |
| Reviewed for Safety.                                  | (b) (4), (b) (6) | 05 Oct 2020 13:32:36 |
| User entered<br>'USA-US127-2020-MRNA-1273-P301000003' | System           | 05 Oct 2020 13:32:04 |

US3742169

Folder: SAE USA-US127-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:04

Serious

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 14 Oct 2020 20:04:55 |
| Reviewed for Safety.   | (b) (4), (b) (6) | 05 Oct 2020 13:32:36 |
| User entered 'Yes (Y)' | System           | 05 Oct 2020 13:32:04 |

US3742169

Folder: SAE USA-US127-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:04

[Death](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 14 Oct 2020 20:04:55 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 05 Oct 2020 13:32:36 |
| User entered 'No (N)' | System           | 05 Oct 2020 13:32:04 |

US3742169

Folder: SAE USA-US127-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:04

[Life threatening](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 14 Oct 2020 20:04:55 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 05 Oct 2020 13:32:36 |
| User entered 'No (N)' | System           | 05 Oct 2020 13:32:04 |



US3742169

Folder: SAE USA-US127-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:04

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 14 Oct 2020 20:04:55 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 05 Oct 2020 13:32:36 |
| User entered 'No (N)' | System           | 05 Oct 2020 13:32:04 |

US3742169

Folder: SAE USA-US127-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:04

[Persistent or significant disability or incapacity](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 14 Oct 2020 20:04:55 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 05 Oct 2020 13:32:36 |
| User entered 'No (N)' | System           | 05 Oct 2020 13:32:04 |

US3742169

Folder: SAE USA-US127-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:04

[Congenital anomaly or birth defect](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 14 Oct 2020 20:04:55 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 05 Oct 2020 13:32:36 |
| User entered 'No (N)' | System           | 05 Oct 2020 13:32:04 |

US3742169

Folder: SAE USA-US127-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:04

[Other medically important event](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 14 Oct 2020 20:04:55 |
| Reviewed for Safety.   | (b) (4), (b) (6) | 05 Oct 2020 13:32:36 |
| User entered 'Yes (Y)' | System           | 05 Oct 2020 13:32:04 |

US3742169

Folder: SAE USA-US127-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:04

[Investigator's First Name](#)

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| DataPoint Verified.  | (b) (4), (b) (6) | 14 Oct 2020 20:04:55 |
| Reviewed for Safety. | (b) (4), (b) (6) | 05 Oct 2020 13:32:36 |
| User entered 'Karen' | System           | 05 Oct 2020 13:32:04 |

US3742169

Folder: SAE USA-US127-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:04

[Investigator's Last Name](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 14 Oct 2020 20:04:55 |
| Reviewed for Safety.   | (b) (4), (b) (6) | 05 Oct 2020 13:32:36 |
| User entered 'Kotloff' | System           | 05 Oct 2020 13:32:04 |

US3742169

Folder: SAE USA-US127-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:04

Site Address: [Street](#)

| Audit                                           | User             | Time (GMT)           |
|-------------------------------------------------|------------------|----------------------|
| DataPoint Verified.                             | (b) (4), (b) (6) | 14 Oct 2020 20:04:55 |
| Reviewed for Safety.                            | (b) (4), (b) (6) | 05 Oct 2020 13:32:36 |
| User entered '685 W. Baltimore Street, HSF 480' | System           | 05 Oct 2020 13:32:04 |

**US3742169**

**Folder: SAE USA-US127-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 11:15:04**

[Site Address: City](#)

| Audit                    | User             | Time (GMT)           |
|--------------------------|------------------|----------------------|
| DataPoint Verified.      | (b) (4), (b) (6) | 14 Oct 2020 20:04:55 |
| Reviewed for Safety.     | (b) (4), (b) (6) | 05 Oct 2020 13:32:36 |
| User entered 'Baltimore' | System           | 05 Oct 2020 13:32:04 |



US3742169

Folder: SAE USA-US127-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:04

Site Address: [Postal Code](#)

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| DataPoint Verified.  | (b) (4), (b) (6) | 14 Oct 2020 20:04:55 |
| Reviewed for Safety. | (b) (4), (b) (6) | 05 Oct 2020 13:32:36 |
| User entered '21201' | System           | 05 Oct 2020 13:32:04 |

US3742169

Folder: SAE USA-US127-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:04

[Investigator Country](#)

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 15 Oct 2020 12:41:34 |
|                      |                  |                      |
| DataPoint Verified.  | (b) (4), (b) (6) | 14 Oct 2020 20:04:55 |
| User entered 'US'    | System           | 05 Oct 2020 13:32:44 |

US3742169

**Folder:** SAE USA-US127-2020-MRNA-1273-P301000003

**Form:** Safety Report Form

**Generated On:** 26 Nov 2020 11:15:04

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '5' | System | 24 Nov 2020 13:31:42 |
| User entered '4' | System | 10 Nov 2020 14:11:30 |
| User entered '3' | System | 16 Oct 2020 00:38:54 |
| User entered '2' | System | 15 Oct 2020 12:41:42 |
| User entered '1' | System | 05 Oct 2020 13:32:44 |

**US3742169**

**Folder: SAE USA-US127-2020-MRNA-1273-P301000003**

**Form: Safety Report Form (3)**

**Generated On: 26 Nov 2020 11:15:04**

[Date of submission \(Pre-filled from custom function\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| DataPoint Verified.              | (b) (4), (b) (6) | 28 Oct 2020 16:00:05 |
| User entered '15/Oct/2020 20:38' | System           | 16 Oct 2020 00:38:54 |

US3742169

Folder: SAE USA-US127-2020-MRNA-1273-P301000003

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 11:15:04

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 10 Nov 2020 14:11:11 |
| DataPoint Verified.  | (b) (4), (b) (6) | 28 Oct 2020 16:00:05 |
| User entered '1'     | (b) (4), (b) (6) | 16 Oct 2020 00:38:54 |
|                      |                  |                      |
|                      |                  |                      |

US3742169

Folder: SAE USA-US127-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:04

[SAEID](#)

| Audit                                                 | User             | Time (GMT)           |
|-------------------------------------------------------|------------------|----------------------|
| DataPoint Verified.                                   | (b) (4), (b) (6) | 14 Oct 2020 20:04:55 |
| Reviewed for Safety.                                  | (b) (4), (b) (6) | 05 Oct 2020 13:32:36 |
| User entered<br>'USA-US127-2020-MRNA-1273-P301000003' | System           | 05 Oct 2020 13:32:04 |

US3742169

Folder: SAE USA-US127-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:04

Serious

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 14 Oct 2020 20:04:55 |
| Reviewed for Safety.   | (b) (4), (b) (6) | 05 Oct 2020 13:32:36 |
| User entered 'Yes (Y)' | System           | 05 Oct 2020 13:32:04 |

US3742169

Folder: SAE USA-US127-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:04

[Death](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 14 Oct 2020 20:04:55 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 05 Oct 2020 13:32:36 |
| User entered 'No (N)' | System           | 05 Oct 2020 13:32:04 |



US3742169

Folder: SAE USA-US127-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:04

[Life threatening](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 14 Oct 2020 20:04:55 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 05 Oct 2020 13:32:36 |
| User entered 'No (N)' | System           | 05 Oct 2020 13:32:04 |

US3742169

Folder: SAE USA-US127-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:04

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 14 Oct 2020 20:04:55 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 05 Oct 2020 13:32:36 |
| User entered 'No (N)' | System           | 05 Oct 2020 13:32:04 |

US3742169

Folder: SAE USA-US127-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:04

[Persistent or significant disability or incapacity](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 14 Oct 2020 20:04:55 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 05 Oct 2020 13:32:36 |
| User entered 'No (N)' | System           | 05 Oct 2020 13:32:04 |

US3742169

Folder: SAE USA-US127-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:04

[Congenital anomaly or birth defect](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 14 Oct 2020 20:04:55 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 05 Oct 2020 13:32:36 |
| User entered 'No (N)' | System           | 05 Oct 2020 13:32:04 |

US3742169

Folder: SAE USA-US127-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:04

[Other medically important event](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 14 Oct 2020 20:04:55 |
| Reviewed for Safety.   | (b) (4), (b) (6) | 05 Oct 2020 13:32:36 |
| User entered 'Yes (Y)' | System           | 05 Oct 2020 13:32:04 |

US3742169

Folder: SAE USA-US127-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:04

[Investigator's First Name](#)

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| DataPoint Verified.  | (b) (4), (b) (6) | 14 Oct 2020 20:04:55 |
| Reviewed for Safety. | (b) (4), (b) (6) | 05 Oct 2020 13:32:36 |
| User entered 'Karen' | System           | 05 Oct 2020 13:32:04 |

US3742169

Folder: SAE USA-US127-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:04

[Investigator's Last Name](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 14 Oct 2020 20:04:55 |
| Reviewed for Safety.   | (b) (4), (b) (6) | 05 Oct 2020 13:32:36 |
| User entered 'Kotloff' | System           | 05 Oct 2020 13:32:04 |

US3742169

Folder: SAE USA-US127-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:04

Site Address: [Street](#)

| Audit                                           | User             | Time (GMT)           |
|-------------------------------------------------|------------------|----------------------|
| DataPoint Verified.                             | (b) (4), (b) (6) | 14 Oct 2020 20:04:55 |
| Reviewed for Safety.                            | (b) (4), (b) (6) | 05 Oct 2020 13:32:36 |
| User entered '685 W. Baltimore Street, HSF 480' | System           | 05 Oct 2020 13:32:04 |



US3742169

Folder: SAE USA-US127-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:04

Site Address: [City](#)

| Audit                    | User             | Time (GMT)           |
|--------------------------|------------------|----------------------|
| DataPoint Verified.      | (b) (4), (b) (6) | 14 Oct 2020 20:04:55 |
| Reviewed for Safety.     | (b) (4), (b) (6) | 05 Oct 2020 13:32:36 |
| User entered 'Baltimore' | System           | 05 Oct 2020 13:32:04 |

US3742169

Folder: SAE USA-US127-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:04

Site Address: [Postal Code](#)

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| DataPoint Verified.  | (b) (4), (b) (6) | 14 Oct 2020 20:04:55 |
| Reviewed for Safety. | (b) (4), (b) (6) | 05 Oct 2020 13:32:36 |
| User entered '21201' | System           | 05 Oct 2020 13:32:04 |

US3742169

Folder: SAE USA-US127-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:04

[Investigator Country](#)

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 15 Oct 2020 12:41:34 |
|                      |                  |                      |
| DataPoint Verified.  | (b) (4), (b) (6) | 14 Oct 2020 20:04:55 |
| User entered 'US'    | System           | 05 Oct 2020 13:32:44 |

US3742169

**Folder:** SAE USA-US127-2020-MRNA-1273-P301000003

**Form:** Safety Report Form

**Generated On:** 26 Nov 2020 11:15:04

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '5' | System | 24 Nov 2020 13:31:42 |
| User entered '4' | System | 10 Nov 2020 14:11:30 |
| User entered '3' | System | 16 Oct 2020 00:38:54 |
| User entered '2' | System | 15 Oct 2020 12:41:42 |
| User entered '1' | System | 05 Oct 2020 13:32:44 |

**US3742169**

**Folder: SAE USA-US127-2020-MRNA-1273-P301000003**

**Form: Safety Report Form (4)**

**Generated On: 26 Nov 2020 11:15:04**

[Date of submission \(Pre-filled from custom function\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| DataPoint Verified.              | (b) (4), (b) (6) | 10 Nov 2020 16:59:47 |
| User entered '10/Nov/2020 14:11' | System           | 10 Nov 2020 14:11:30 |

US3742169

Folder: SAE USA-US127-2020-MRNA-1273-P301000003

Form: Safety Report Form (4)

Generated On: 26 Nov 2020 11:15:04

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 24 Nov 2020 13:31:28 |
| DataPoint Verified.  | (b) (4), (b) (6) | 10 Nov 2020 16:59:47 |
| User entered '1'     | (b) (4), (b) (6) | 10 Nov 2020 14:11:30 |

US3742169

Folder: SAE USA-US127-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:04

[SAEID](#)

| Audit                                                 | User             | Time (GMT)           |
|-------------------------------------------------------|------------------|----------------------|
| DataPoint Verified.                                   | (b) (4), (b) (6) | 14 Oct 2020 20:04:55 |
| Reviewed for Safety.                                  | (b) (4), (b) (6) | 05 Oct 2020 13:32:36 |
| User entered<br>'USA-US127-2020-MRNA-1273-P301000003' | System           | 05 Oct 2020 13:32:04 |

US3742169

Folder: SAE USA-US127-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:04

Serious

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 14 Oct 2020 20:04:55 |
| Reviewed for Safety.   | (b) (4), (b) (6) | 05 Oct 2020 13:32:36 |
| User entered 'Yes (Y)' | System           | 05 Oct 2020 13:32:04 |



US3742169

Folder: SAE USA-US127-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:04

[Death](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 14 Oct 2020 20:04:55 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 05 Oct 2020 13:32:36 |
| User entered 'No (N)' | System           | 05 Oct 2020 13:32:04 |

US3742169

Folder: SAE USA-US127-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:04

[Life threatening](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 14 Oct 2020 20:04:55 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 05 Oct 2020 13:32:36 |
| User entered 'No (N)' | System           | 05 Oct 2020 13:32:04 |

US3742169

Folder: SAE USA-US127-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:04

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 14 Oct 2020 20:04:55 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 05 Oct 2020 13:32:36 |
| User entered 'No (N)' | System           | 05 Oct 2020 13:32:04 |

US3742169

Folder: SAE USA-US127-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:04

[Persistent or significant disability or incapacity](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 14 Oct 2020 20:04:55 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 05 Oct 2020 13:32:36 |
| User entered 'No (N)' | System           | 05 Oct 2020 13:32:04 |

US3742169

Folder: SAE USA-US127-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:04

[Congenital anomaly or birth defect](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 14 Oct 2020 20:04:55 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 05 Oct 2020 13:32:36 |
| User entered 'No (N)' | System           | 05 Oct 2020 13:32:04 |

US3742169

Folder: SAE USA-US127-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:04

[Other medically important event](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 14 Oct 2020 20:04:55 |
| Reviewed for Safety.   | (b) (4), (b) (6) | 05 Oct 2020 13:32:36 |
| User entered 'Yes (Y)' | System           | 05 Oct 2020 13:32:04 |

US3742169

Folder: SAE USA-US127-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:04

[Investigator's First Name](#)

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| DataPoint Verified.  | (b) (4), (b) (6) | 14 Oct 2020 20:04:55 |
| Reviewed for Safety. | (b) (4), (b) (6) | 05 Oct 2020 13:32:36 |
| User entered 'Karen' | System           | 05 Oct 2020 13:32:04 |

US3742169

Folder: SAE USA-US127-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:04

[Investigator's Last Name](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 14 Oct 2020 20:04:55 |
| Reviewed for Safety.   | (b) (4), (b) (6) | 05 Oct 2020 13:32:36 |
| User entered 'Kotloff' | System           | 05 Oct 2020 13:32:04 |



US3742169

Folder: SAE USA-US127-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:04

Site Address: [Street](#)

| Audit                                           | User             | Time (GMT)           |
|-------------------------------------------------|------------------|----------------------|
| DataPoint Verified.                             | (b) (4), (b) (6) | 14 Oct 2020 20:04:55 |
| Reviewed for Safety.                            | (b) (4), (b) (6) | 05 Oct 2020 13:32:36 |
| User entered '685 W. Baltimore Street, HSF 480' | System           | 05 Oct 2020 13:32:04 |

US3742169

Folder: SAE USA-US127-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:04

Site Address: [City](#)

| Audit                    | User             | Time (GMT)           |
|--------------------------|------------------|----------------------|
| DataPoint Verified.      | (b) (4), (b) (6) | 14 Oct 2020 20:04:55 |
| Reviewed for Safety.     | (b) (4), (b) (6) | 05 Oct 2020 13:32:36 |
| User entered 'Baltimore' | System           | 05 Oct 2020 13:32:04 |

US3742169

Folder: SAE USA-US127-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:04

Site Address: [Postal Code](#)

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| DataPoint Verified.  | (b) (4), (b) (6) | 14 Oct 2020 20:04:55 |
| Reviewed for Safety. | (b) (4), (b) (6) | 05 Oct 2020 13:32:36 |
| User entered '21201' | System           | 05 Oct 2020 13:32:04 |

US3742169

Folder: SAE USA-US127-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:04

[Investigator Country](#)

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 15 Oct 2020 12:41:34 |
|                      |                  |                      |
| DataPoint Verified.  | (b) (4), (b) (6) | 14 Oct 2020 20:04:55 |
| User entered 'US'    | System           | 05 Oct 2020 13:32:44 |

US3742169

**Folder:** SAE USA-US127-2020-MRNA-1273-P301000003

**Form:** Safety Report Form

**Generated On:** 26 Nov 2020 11:15:04

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '5' | System | 24 Nov 2020 13:31:42 |
| User entered '4' | System | 10 Nov 2020 14:11:30 |
| User entered '3' | System | 16 Oct 2020 00:38:54 |
| User entered '2' | System | 15 Oct 2020 12:41:42 |
| User entered '1' | System | 05 Oct 2020 13:32:44 |

**US3742169**

**Folder: SAE USA-US127-2020-MRNA-1273-P301000003**

**Form: Safety Report Form (5)**

**Generated On: 26 Nov 2020 11:15:04**

[Date of submission \(Pre-filled from custom function\)](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '24/Nov/2020 08:31' | System | 24 Nov 2020 13:31:42 |

US3742169

Folder: SAE USA-US127-2020-MRNA-1273-P301000003

Form: Safety Report Form (5)

Generated On: 26 Nov 2020 11:15:04

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

| Audit            | User             | Time (GMT)           |
|------------------|------------------|----------------------|
| User entered '1' | (b) (4), (b) (6) | 24 Nov 2020 13:31:42 |
|                  |                  |                      |