

US3532063 (Prod: Children's Healthcare of Atlanta)

Generated By: (b) (6)

Generated On: 26 Nov 2020 09:35:30

All time stamps listed in this document are displayed in GMT

US3532063

**Form: Participant Creation**

**Generated On: 26 Nov 2020 09:35:30**

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[Participant ID](#)

US3532063

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

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Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:35:30

|                                                                 |                                         |
|-----------------------------------------------------------------|-----------------------------------------|
| Was this visit performed?                                       | Yes <input checked="" type="radio"/>    |
|                                                                 | No <input type="radio"/>                |
| Visit date (dd MMM yyyy)                                        | 18 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 09:35:30

|                                           |                                                                                                                                                                            |
|-------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Date of Birth (MMM yyyy)                  | (b) (6) 1949                                                                                                                                                               |
| Age                                       | 70                                                                                                                                                                         |
| Age Units                                 | YEARS                                                                                                                                                                      |
| Age (Derived)                             | 70                                                                                                                                                                         |
| Sex                                       | Female <input checked="" type="radio"/><br>Male <input 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                                     | True                                                                                                                                                                       |
| Black                                     | False                                                                                                                                                                      |
| Asian                                     | False                                                                                                                                                                      |
| 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 09:35:30

|                                                 |                                              |
|-------------------------------------------------|----------------------------------------------|
| Date of Informed Consent ( <i>dd MMM yyyy</i> ) | 18 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 checked="" type="radio"/> |
|                                                 | Amendment 3 <input 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 09:35:30

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 09:35:30

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:35:30

|                                                   |                                      |
|---------------------------------------------------|--------------------------------------|
| Condition                                         | OSTEOARTHRITIS                       |
|                                                   | NECK AND LEGS                        |
| Start date (dd MMM yyyy)                          | UN UNK 2000                          |
| Start date completely unknown                     | False                                |
| Condition ongoing at study entry                  | Yes <input checked="" type="radio"/> |
|                                                   | 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 (2)

Generated On: 26 Nov 2020 09:35:30

|                                                   |                                                                  |
|---------------------------------------------------|------------------------------------------------------------------|
| Condition                                         | GANGLION CYST                                                    |
| Start date (dd MMM yyyy)                          |                                                                  |
| Start date completely unknown                     | True                                                             |
| Condition ongoing at study entry                  | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| If No, please specify the stop date (dd MMM yyyy) | UN UNK 1978                                                      |
| Stop date completely unknown                      | False                                                            |
| Start Month and Year (derived)                    |                                                                  |
| Start Year (derived)                              |                                                                  |
| Stop Month and Year (derived)                     | JAN 1978                                                         |
| Stop Year (derived)                               | 1978                                                             |

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Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:35:30

|                                                   |                                                                  |
|---------------------------------------------------|------------------------------------------------------------------|
| Condition                                         | CYST ON NECK<br>BENIGN                                           |
| Start date (dd MMM yyyy)                          | UN UNK 2017                                                      |
| Start date completely unknown                     | False                                                            |
| Condition ongoing at study entry                  | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| If No, please specify the stop date (dd MMM yyyy) | UN UNK 2017                                                      |
| Stop date completely unknown                      | False                                                            |
| Start Month and Year (derived)                    | JAN 2017                                                         |
| Start Year (derived)                              | 2017                                                             |
| Stop Month and Year (derived)                     | JAN 2017                                                         |
| Stop Year (derived)                               | 2017                                                             |

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Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:35:30

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

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Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:35:30

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

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Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:35:30

|                                                   |                                                                  |
|---------------------------------------------------|------------------------------------------------------------------|
| Condition                                         | LATEX ALLERGY                                                    |
| 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 (7)

Generated On: 26 Nov 2020 09:35:30

|                                                         |                                                                  |
|---------------------------------------------------------|------------------------------------------------------------------|
| Condition                                               | MENOPAUSE                                                        |
| 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: Vital Signs

Generated On: 26 Nov 2020 09:35:30

|                                           |                                      |
|-------------------------------------------|--------------------------------------|
| Were vital signs assessed?                | Yes <input checked="" type="radio"/> |
|                                           | No <input type="radio"/>             |
| Date of assessment ( <i>dd MMM yyyy</i> ) | 18 AUG 2020                          |
| Time of assessment ( <i>00:00-23:59</i> ) | 13:49 (24 HR)                        |
| Vital Signs Date and Time (derived)       | 18 AUG 2020 13:49                    |
| Height ( <i>xxx.x</i> )                   | 169.5 cm                             |
| Weight ( <i>xxx.x</i> )                   | 49.9 kg                              |
| BMI ( <i>xxx.x</i> )                      | 17.36845 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 09:35:30

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: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:35:30

|                                                                      |                                                   |
|----------------------------------------------------------------------|---------------------------------------------------|
| Date of assessment ( <i>dd MMM yyyy</i> )                            | 18 AUG 2020                                       |
| Is the participant of childbearing potential?                        | Yes <input type="radio"/>                         |
|                                                                      | No <input checked="" type="radio"/>               |
| If No, what is the reason?                                           | Surgically sterile <input type="radio"/>          |
|                                                                      | Post-menopausal <input checked="" type="radio"/>  |
|                                                                      | Partner medically sterile <input type="radio"/>   |
|                                                                      | Not reached age of Menarche <input type="radio"/> |
|                                                                      | Other <input type="radio"/>                       |
| If Partner medically sterile or Other, specify _____                 |                                                   |
| If Surgically sterile, date of surgery ( <i>dd MMM yyyy</i> ) _____  |                                                   |
| Date of surgery unknown                                              | False                                             |
| If Post-menopausal, date of last menstruation ( <i>dd MMM yyyy</i> ) | UN UNK 2000                                       |
| Date of last menstruation unknown                                    | False                                             |

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Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:35:30

#### 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 type="radio"/>           |
|                                                                                                                                                         | No <input checked="" 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>                                                                                                                    | False |
| <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 09:35:30

|                                                                                                                                        |       |
|----------------------------------------------------------------------------------------------------------------------------------------|-------|
| <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) | True  |
| <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 09:35:30

|                                                                 |                                         |
|-----------------------------------------------------------------|-----------------------------------------|
| Was this visit performed?                                       | Yes <input checked="" type="radio"/>    |
|                                                                 | No <input type="radio"/>                |
| Visit date (dd MMM yyyy)                                        | 18 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 09:35:30

What was the date of randomization? (dd MMM yyyy) 18 AUG 2020

What was the participant's randomization number? 186760

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 09:35:30

|        |               |
|--------|---------------|
| 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 09:35:30

|                                     |                                                                                                        |
|-------------------------------------|--------------------------------------------------------------------------------------------------------|
| 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)    | 18 AUG 2020                                                                                            |
| Time of assessment (00:00-23:59)    | 13:45 (24 HR)                                                                                          |
| Vital Signs Date and Time (derived) | 18 AUG 2020 13:45                                                                                      |
| Temperature (xxx.x)                 | 97.1 F                                                                                                 |
| Route of measurement                | Oral <input checked="" type="radio"/><br>Axillary <input type="radio"/><br>Other <input type="radio"/> |
| If Other, specify                   |                                                                                                        |
| Pulse (xxx)                         | 76 beats/min                                                                                           |
| Pulse units                         | BPM                                                                                                    |
| Respiratory Rate (xxx)              | 18 breaths/min                                                                                         |
| Respiratory Rate units              | BREATHS/MIN                                                                                            |
| Systolic Blood Pressure (xxx)       | 103 mmHg                                                                                               |
| Systolic Blood Pressure units       | MMHG                                                                                                   |
| Diastolic Blood Pressure (xxx)      | 64 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 09:35:30

|                                     |                                                                                                        |
|-------------------------------------|--------------------------------------------------------------------------------------------------------|
| 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)    | 18 AUG 2020                                                                                            |
| Time of assessment (00:00-23:59)    | 15:20 (24 HR)                                                                                          |
| Vital Signs Date and Time (derived) | 18 AUG 2020 15:20                                                                                      |
| Temperature (xxx.x)                 | 97.4 F                                                                                                 |
| Route of measurement                | Oral <input checked="" type="radio"/><br>Axillary <input type="radio"/><br>Other <input type="radio"/> |
| If Other, specify                   |                                                                                                        |
| Pulse (xxx)                         | 65 beats/min                                                                                           |
| Pulse units                         | BPM                                                                                                    |
| Respiratory Rate (xxx)              | 18 breaths/min                                                                                         |
| Respiratory Rate units              | BREATHS/MIN                                                                                            |
| Systolic Blood Pressure (xxx)       | 115 mmHg                                                                                               |
| Systolic Blood Pressure units       | MMHG                                                                                                   |
| Diastolic Blood Pressure (xxx)      | 76 mmHg                                                                                                |
| Diastolic Blood Pressure units      | MMHG                                                                                                   |



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Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 09:35:30

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

18 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: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:35:30

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 18 AUG 2020

What was the treatment time? (00:00-23:59) 14:41 (24 HR)

Treatment Date and Time (derived) 18 AUG 2020 14:41

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

What was the frequency of the study treatment dosing? ONCE

What was the route of administration for the study treatment? INTRAMUSCULAR

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:35:30

|                                        |                                      |
|----------------------------------------|--------------------------------------|
| Was the sample collected?              | Yes <input checked="" type="radio"/> |
|                                        | No <input type="radio"/>             |
| Collection date ( <i>dd MMM yyyy</i> ) | 18 AUG 2020                          |
| Collection time ( <i>00:00-23:59</i> ) | 14:21 (24 HR)                        |
| Collection date and time (derived)     | 18 AUG 2020 14:21                    |

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:35:30

|                                        |                           |                                          |                                    |
|----------------------------------------|---------------------------|------------------------------------------|------------------------------------|
| Collection date ( <i>dd MMM yyyy</i> ) |                           |                                          | 18 AUG 2020                        |
| Lab Test                               | Was the sample collected? | Collection time ( <i>00:00 - 23:59</i> ) | Collection date and time (derived) |
| Nasopharyngeal Swab 1                  | Yes                       | 14:11                                    | 18 AUG 2020 14:11                  |
| Nasopharyngeal Swab 2                  | No                        |                                          |                                    |

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Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 09:35:30

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 09:35:30

---

**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

97.5 °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 18 AUG 2020 15:21

---

PC Open Date & Time 18 AUG 2020 15:01

---

PC Close Date & Time 18 AUG 2020 17:31

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 26 Nov 2020 09:35:30

**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

96.8 °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 18 AUG 2020 21:15

PC Open Date & Time 18 AUG 2020 18:26

PC Close Date & Time 19 AUG 2020 11:59

US3532063

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 09:35:30

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**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

97.5 °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

19 AUG 2020 21:18

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59



US3532063

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 26 Nov 2020 09:35:30

**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

97.7 °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

20 AUG 2020 20:06

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59

US3532063

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 09:35:30

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**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

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

21 AUG 2020 22:02

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

US3532063

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 26 Nov 2020 09:35:30

**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

96.2 °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

22 AUG 2020 21:27

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3532063

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 26 Nov 2020 09:35:30

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**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

96.7 °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

23 AUG 2020 21:28

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3532063

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 26 Nov 2020 09:35:30

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**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

96.8 °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

25 AUG 2020 01:15

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3532063

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 09:35:30

**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

18 AUG 2020 15:22

PC Open Date & Time

18 AUG 2020 15:01

PC Close Date & Time

18 AUG 2020 17:31

US3532063

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 26 Nov 2020 09:35:30

**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

18 AUG 2020 21:16

PC Open Date & Time

18 AUG 2020 18:26

PC Close Date & Time

19 AUG 2020 11:59

US3532063

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 26 Nov 2020 09:35:30

**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 ☒

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

19 AUG 2020 21:19

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59



US3532063

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 26 Nov 2020 09:35:30

**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 ☒

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

Yes ☒

No ☐

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

8

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

20 AUG 2020 20:08

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59

US3532063

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 26 Nov 2020 09:35:30

**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

21 AUG 2020 22:04

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

US3532063

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 26 Nov 2020 09:35:30

**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 ☒

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

22 AUG 2020 21:28

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3532063

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 26 Nov 2020 09:35:30

**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

23 AUG 2020 21:28

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3532063

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 26 Nov 2020 09:35:30

**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

25 AUG 2020 01:15

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3532063

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 09:35:30

**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 ☐

US3532063

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 09:35:30

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

No ☒

Yes ☐

|                      |                   |
|----------------------|-------------------|
| PC Time stamp        | 18 AUG 2020 15:23 |
| PC Open Date & Time  | 18 AUG 2020 15:01 |
| PC Close Date & Time | 18 AUG 2020 17:31 |

US3532063

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 09:35:30

**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 ☐



US3532063

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 09:35:30

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

No ☒

Yes ☐

|                      |                   |
|----------------------|-------------------|
| PC Time stamp        | 18 AUG 2020 21:17 |
| PC Open Date & Time  | 18 AUG 2020 18:26 |
| PC Close Date & Time | 19 AUG 2020 11:59 |

US3532063

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 09:35:30

**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 ☒

US3532063

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 09:35:30

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 19 AUG 2020 21:20 |
| PC Open Date & Time          | 19 AUG 2020 12:00 |
| PC Close Date & Time         | 20 AUG 2020 11:59 |

US3532063

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 09:35:30

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 ☒

US3532063

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 09:35:30

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 20 AUG 2020 20:09 |
| PC Open Date & Time          | 20 AUG 2020 12:00 |
| PC Close Date & Time         | 21 AUG 2020 11:59 |

US3532063

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 09:35:30

**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 ☒

US3532063

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 09:35:30

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 21 AUG 2020 22:05 |
| PC Open Date & Time          | 21 AUG 2020 12:00 |
| PC Close Date & Time         | 22 AUG 2020 11:59 |

US3532063

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 09:35:30

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 ☒



US3532063

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 09:35:30

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 22 AUG 2020 21:29 |
| PC Open Date & Time          | 22 AUG 2020 12:00 |
| PC Close Date & Time         | 23 AUG 2020 11:59 |

US3532063

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 09:35:30

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 ☒

US3532063

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 09:35:30

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 23 AUG 2020 21:29 |
| PC Open Date & Time          | 23 AUG 2020 12:00 |
| PC Close Date & Time         | 24 AUG 2020 11:59 |

US3532063

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 09:35:30

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 ☒

US3532063

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 09:35:30

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 25 AUG 2020 01:15 |
| PC Open Date & Time          | 24 AUG 2020 12:00 |
| PC Close Date & Time         | 25 AUG 2020 11:59 |

US3532063

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:35:30

Was Contact Attempted?

Yes ☒

No ☐

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

26 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3532063

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:35:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3532063

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:35:30

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

2 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3532063

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:35:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3532063

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:35:30

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

10 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3532063

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:35:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3532063

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:35:30

|                                                                 |                                         |
|-----------------------------------------------------------------|-----------------------------------------|
| Was this visit performed?                                       | Yes <input checked="" type="radio"/>    |
|                                                                 | No <input type="radio"/>                |
| Visit date (dd MMM yyyy)                                        | 16 SEP 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                                  |

US3532063

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:35:30

|                                     |                                           |
|-------------------------------------|-------------------------------------------|
| 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)    | 16 SEP 2020                               |
| Time of assessment (00:00-23:59)    | 14:09 (24 HR)                             |
| Vital Signs Date and Time (derived) | 16 SEP 2020 14:09                         |
| Temperature (xxx.x)                 | 98.3 F                                    |
| Route of measurement                | Oral <input checked="" type="radio"/>     |
|                                     | Axillary <input type="radio"/>            |
|                                     | Other <input type="radio"/>               |
| If Other, specify                   |                                           |
| Pulse (xxx)                         | 73 beats/min                              |
| Pulse units                         | BPM                                       |
| Respiratory Rate (xxx)              | 16 breaths/min                            |
| Respiratory Rate units              | BREATHS/MIN                               |
| Systolic Blood Pressure (xxx)       | 105 mmHg                                  |
| Systolic Blood Pressure units       | MMHG                                      |
| Diastolic Blood Pressure (xxx)      | 63 mmHg                                   |
| Diastolic Blood Pressure units      | MMHG                                      |

US3532063

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:35:30

|                                     |                                            |
|-------------------------------------|--------------------------------------------|
| Timepoint                           | Pre-Dose <input type="radio"/>             |
|                                     | Post-Dose <input checked="" type="radio"/> |
| Were vital signs assessed?          | Yes <input checked="" type="radio"/>       |
|                                     | No <input type="radio"/>                   |
| Date of assessment (dd MMM yyyy)    | 16 SEP 2020                                |
| Time of assessment (00:00-23:59)    | 15:43 (24 HR)                              |
| Vital Signs Date and Time (derived) | 16 SEP 2020 15:43                          |
| Temperature (xxx.x)                 | 97.9 F                                     |
| Route of measurement                | Oral <input checked="" type="radio"/>      |
|                                     | Axillary <input type="radio"/>             |
|                                     | Other <input type="radio"/>                |
| If Other, specify                   |                                            |
| Pulse (xxx)                         | 66 beats/min                               |
| Pulse units                         | BPM                                        |
| Respiratory Rate (xxx)              | 16 breaths/min                             |
| Respiratory Rate units              | BREATHS/MIN                                |
| Systolic Blood Pressure (xxx)       | 109 mmHg                                   |
| Systolic Blood Pressure units       | MMHG                                       |
| Diastolic Blood Pressure (xxx)      | 67 mmHg                                    |
| Diastolic Blood Pressure units      | MMHG                                       |

US3532063

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:35:30

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

16 SEP 2020

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

US3532063

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:35:30

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 16 SEP 2020

What was the treatment time? (00:00-23:59) 15:11 (24 HR)

Treatment Date and Time (derived) 16 SEP 2020 15:11

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

What was the frequency of the study treatment dosing? ONCE

What was the route of administration for the study treatment? INTRAMUSCULAR



US3532063

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:35:30

|                                        |                                      |
|----------------------------------------|--------------------------------------|
| Was the sample collected?              | Yes <input checked="" type="radio"/> |
|                                        | No <input type="radio"/>             |
| Collection date ( <i>dd MMM yyyy</i> ) | 16 SEP 2020                          |
| Collection time ( <i>00:00-23:59</i> ) | 14:50 (24 HR)                        |
| Collection date and time (derived)     | 16 SEP 2020 14:50                    |

US3532063

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:35:30

|                                        |                           |                                          |                                    |
|----------------------------------------|---------------------------|------------------------------------------|------------------------------------|
| Collection date ( <i>dd MMM yyyy</i> ) |                           |                                          | 16 SEP 2020                        |
| Lab Test                               | Was the sample collected? | Collection time ( <i>00:00 - 23:59</i> ) | Collection date and time (derived) |
| Nasopharyngeal Swab 1                  | Yes                       | 14:37                                    | 16 SEP 2020 14:37                  |
| Nasopharyngeal Swab 2                  | No                        |                                          |                                    |

US3532063

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:35:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3532063

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 26 Nov 2020 09:35:30

**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

97.9 °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 16 SEP 2020 15:43

PC Open Date & Time 16 SEP 2020 15:31

PC Close Date & Time 16 SEP 2020 18:01

US3532063

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 26 Nov 2020 09:35:30

**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 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        | 16 SEP 2020 21:21 |
| PC Open Date & Time  | 16 SEP 2020 18:56 |
| PC Close Date & Time | 17 SEP 2020 11:59 |

US3532063

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 09:35:30

---

**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

96.5 °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

17 SEP 2020 21:49

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3532063

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 26 Nov 2020 09:35:30

---

**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

96.5 °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

19 SEP 2020 04:43

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3532063

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 09:35:30

---

**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

95.4 °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

19 SEP 2020 20:59

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59



US3532063

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 26 Nov 2020 09:35:30

**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

96.4 °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

20 SEP 2020 21:06

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3532063

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 26 Nov 2020 09:35:30

**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

97.1 °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

21 SEP 2020 21:20

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3532063

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 26 Nov 2020 09:35:30

---

**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

97.1 °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

22 SEP 2020 21:02

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3532063

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 09:35:30

**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

16 SEP 2020 15:44

PC Open Date & Time

16 SEP 2020 15:31

PC Close Date & Time

16 SEP 2020 18:01

US3532063

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 26 Nov 2020 09:35:30

**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

16 SEP 2020 21:22

PC Open Date & Time

16 SEP 2020 18:56

PC Close Date & Time

17 SEP 2020 11:59

US3532063

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 26 Nov 2020 09:35:30

**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 ☒

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

17 SEP 2020 21:51

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3532063

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 26 Nov 2020 09:35:30

**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 ☒

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

19 SEP 2020 04:44

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3532063

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 26 Nov 2020 09:35:30

| TIMEPOINT                                                                                         | DAY 4                                                                                                            |
|---------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------|
| Please record - <b>PAIN AT INJECTION SITE.</b><br>Please select one response below                | None <input checked="" type="radio"/>                                                                            |
|                                                                                                   | Does not interfere with activity <input type="radio"/>                                                           |
|                                                                                                   | Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity <input type="radio"/>      |
|                                                                                                   | Any use of prescription pain reliever or prevents daily activity <input type="radio"/>                           |
| Is there any <b>REDNESS AT INJECTION SITE?</b>                                                    | Yes <input type="radio"/>                                                                                        |
|                                                                                                   | No <input checked="" type="radio"/>                                                                              |
| Is there any <b>SWELLING/HARDNESS AT INJECTION SITE?</b>                                          | Yes <input checked="" type="radio"/>                                                                             |
|                                                                                                   | No <input type="radio"/>                                                                                         |
| Please record - <b>SWELLING/HARDNESS AT INJECTION SITE (in mm)</b>                                | 300                                                                                                              |
| Measure the largest size across any injection site swelling/hardness with the ruler provided.     |                                                                                                                  |
| Please record - <b>UNDERARM GLAND SWELLING OR TENDERNESS.</b><br>Please select one response below | None <input checked="" type="radio"/>                                                                            |
|                                                                                                   | Does not interfere with activity <input type="radio"/>                                                           |
|                                                                                                   | Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity <input type="radio"/> |
|                                                                                                   | Any use of prescription pain reliever or prevents daily activity <input type="radio"/>                           |
| PC Time Stamp                                                                                     | 19 SEP 2020 21:02                                                                                                |
| PC Open Date & Time                                                                               | 19 SEP 2020 12:00                                                                                                |
| PC Close Date & Time                                                                              | 20 SEP 2020 11:59                                                                                                |



US3532063

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 26 Nov 2020 09:35:30

**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 ☒

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

20 SEP 2020 21:08

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3532063

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 26 Nov 2020 09:35:30

**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

21 SEP 2020 21:22

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3532063

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 26 Nov 2020 09:35:30

**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

22 SEP 2020 21:02

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3532063

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 09:35:30

**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 ☐

US3532063

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 09:35:30

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

No ☒

Yes ☐

|                      |                   |
|----------------------|-------------------|
| PC Time stamp        | 16 SEP 2020 15:45 |
| PC Open Date & Time  | 16 SEP 2020 15:31 |
| PC Close Date & Time | 16 SEP 2020 18:01 |

US3532063

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 09:35:30

**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 ☐

US3532063

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 09:35:30

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

No ☒

Yes ☐

|                      |                   |
|----------------------|-------------------|
| PC Time stamp        | 16 SEP 2020 21:23 |
| PC Open Date & Time  | 16 SEP 2020 18:56 |
| PC Close Date & Time | 17 SEP 2020 11:59 |

US3532063

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 09:35:30

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 ☒



US3532063

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 09:35:30

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 17 SEP 2020 21:52 |
| PC Open Date & Time          | 17 SEP 2020 12:00 |
| PC Close Date & Time         | 18 SEP 2020 11:59 |

US3532063

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 09:35:30

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 ☒

US3532063

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 09:35:30

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 19 SEP 2020 04:44 |
| PC Open Date & Time          | 18 SEP 2020 12:00 |
| PC Close Date & Time         | 19 SEP 2020 11:59 |

US3532063

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 09:35:30

**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 ☒

US3532063

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 09:35:30

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 19 SEP 2020 21:02 |
| PC Open Date & Time          | 19 SEP 2020 12:00 |
| PC Close Date & Time         | 20 SEP 2020 11:59 |

US3532063

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 09:35:30

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 ☒

US3532063

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 09:35:30

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 20 SEP 2020 21:08 |
| PC Open Date & Time          | 20 SEP 2020 12:00 |
| PC Close Date & Time         | 21 SEP 2020 11:59 |

US3532063

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 09:35:30

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 ☒



US3532063

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 09:35:30

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 21 SEP 2020 21:22 |
| PC Open Date & Time          | 21 SEP 2020 12:00 |
| PC Close Date & Time         | 22 SEP 2020 11:59 |

US3532063

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 09:35:30

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 ☒

US3532063

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 09:35:30

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 22 SEP 2020 21:03 |
| PC Open Date & Time          | 22 SEP 2020 12:00 |
| PC Close Date & Time         | 23 SEP 2020 11:59 |

US3532063

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:35:30

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

26 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3532063

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:35:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3532063

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:35:30

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

3 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3532063

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:35:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3532063

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:35:30

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

10 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3532063

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:35:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3532063

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:35:30

|                                                                 |                                         |
|-----------------------------------------------------------------|-----------------------------------------|
| Was this visit performed?                                       | Yes <input checked="" type="radio"/>    |
|                                                                 | No <input type="radio"/>                |
| Visit date (dd MMM yyyy)                                        | 14 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                                                      | VISIT3                                  |

US3532063

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:35:30

|                                           |                                       |
|-------------------------------------------|---------------------------------------|
| Were vital signs assessed?                | Yes <input checked="" type="radio"/>  |
|                                           | No <input type="radio"/>              |
| Date of assessment ( <i>dd MMM yyyy</i> ) | 14 OCT 2020                           |
| Time of assessment ( <i>00:00-23:59</i> ) | 13:36 (24 HR)                         |
| Vital Signs Date and Time (derived)       | 14 OCT 2020 13:36                     |
| Temperature ( <i>xxx.x</i> )              | 97.9 F                                |
| Route of measurement                      | Oral <input checked="" type="radio"/> |
|                                           | Axillary <input type="radio"/>        |
|                                           | Other <input type="radio"/>           |
| If Other, specify                         |                                       |
| Pulse ( <i>xxx</i> )                      | 65 beats/min                          |
| Pulse units                               | BPM                                   |
| Respiratory Rate ( <i>xxx</i> )           | 14 breaths/min                        |
| Respiratory Rate units                    | BREATHS/MIN                           |
| Systolic Blood Pressure ( <i>xxx</i> )    | 113 mmHg                              |
| Systolic Blood Pressure units             | MMHG                                  |
| Diastolic Blood Pressure ( <i>xxx</i> )   | 74 mmHg                               |
| Diastolic Blood Pressure units            | MMHG                                  |
| Height (derived)                          |                                       |
| Weight (derived)                          |                                       |

US3532063

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:35:30

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.*

US3532063

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:35:30

|                                        |                                      |
|----------------------------------------|--------------------------------------|
| Was the sample collected?              | Yes <input checked="" type="radio"/> |
|                                        | No <input type="radio"/>             |
| Collection date ( <i>dd MMM yyyy</i> ) | 14 OCT 2020                          |
| Collection time ( <i>00:00-23:59</i> ) | 13:54 (24 HR)                        |
| Collection date and time (derived)     | 14 OCT 2020 13:54                    |

US3532063

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:35:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3532063

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:30

|                                                                                                                                                                                 |                                                                  |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------|
| <b>TIMEPOINT</b>                                                                                                                                                                | 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 checked="" 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 checked="" type="radio"/><br>Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):                                                                           |                                                                  |
| Date and time of submission                                                                                                                                                     | 18 OCT 2020 12:04:16                                             |
| Patient Cloud Open Date & Time                                                                                                                                                  | 18 OCT 2020 00:01                                                |
| Patient Cloud Close Date & Time                                                                                                                                                 | 22 OCT 2020 23:59                                                |

US3532063

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:30

**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 ☒

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

25 OCT 2020 07:39:59

Patient Cloud Open Date & Time

25 OCT 2020 00:01

Patient Cloud Close Date & Time

29 OCT 2020 23:59



US3532063

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:30

| 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 <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                                                                                                                                                     | 02 NOV 2020 18:10:23                                                                                           |
| Patient Cloud Open Date & Time                                                                                                                                                  | 01 NOV 2020 00:01                                                                                              |
| Patient Cloud Close Date & Time                                                                                                                                                 | 05 NOV 2020 23:59                                                                                              |

US3532063

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:30

**TIMEPOINT**

DAY 92

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

15 NOV 2020 07:23:35

Patient Cloud Open Date & Time

15 NOV 2020 00:01

Patient Cloud Close Date & Time

19 NOV 2020 23:59

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:30

| 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"/>                                               |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 OCT 2020 00:01

[Patient Cloud Close Date & Time](#)

19 OCT 2020 23:59

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:30

| 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"/>                                               |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 OCT 2020 00:01

[Patient Cloud Close Date & Time](#)

26 OCT 2020 23:59

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:30

| 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"/>                                               |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 OCT 2020 00:01

[Patient Cloud Close Date & Time](#)

02 NOV 2020 23:59



US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:30

| 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 <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"/>                                               |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

09 NOV 2020 23:59

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:30

| 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"/>                                               |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

16 NOV 2020 23:59

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:30

|                                                                                                                                                                                 |                                                                  |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------|
| <b>TIMEPOINT</b>                                                                                                                                                                | 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 checked="" 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 checked="" type="radio"/><br>Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):                                                                           |                                                                  |
| Date and time of submission                                                                                                                                                     | 21 NOV 2020 14:24:12                                             |
| Patient Cloud Open Date & Time                                                                                                                                                  | 19 NOV 2020 00:01                                                |
| Patient Cloud Close Date & Time                                                                                                                                                 | 23 NOV 2020 23:59                                                |

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:30

| 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"/>                                               |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

30 NOV 2020 23:59

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:30

| 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"/>                                               |



US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

07 DEC 2020 23:59

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:30

| 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"/>                                               |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

14 DEC 2020 23:59

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:30

| 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"/>                                               |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

21 DEC 2020 23:59

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:30

| 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"/>                                               |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

28 DEC 2020 23:59

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:30

| 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"/>                                               |



US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

04 JAN 2021 23:59

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:30

| 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"/>                                               |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

11 JAN 2021 23:59

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:30

| 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"/>                                               |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

18 JAN 2021 23:59

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:30

| 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 <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"/>                                               |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

25 JAN 2021 23:59

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:30

**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 ☐ 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 ☐



US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

01 FEB 2021 23:59

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:30

**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 ☐ 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 ☐

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

08 FEB 2021 23:59

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:30

| 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"/>                                               |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

15 FEB 2021 23:59

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:30

| 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"/>                                               |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

22 FEB 2021 23:59

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:30

| 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"/>                                               |



US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

01 MAR 2021 23:59

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:30

| 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"/>                                               |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 MAR 2021 00:01

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08 MAR 2021 23:59

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:30

| 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"/>                                               |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

15 MAR 2021 23:59

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:30

| 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"/>                                               |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

22 MAR 2021 23:59

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:30

| 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"/>                                               |



US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

29 MAR 2021 23:59

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:30

| 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"/>                                               |

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

05 APR 2021 23:59

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:30

| 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"/>                                               |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

12 APR 2021 23:59

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:30

| 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"/>                                               |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

19 APR 2021 23:59

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:30

| 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"/>                                               |



US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

26 APR 2021 23:59

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:30

| 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"/>                                               |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

03 MAY 2021 23:59

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:30

| 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"/>                                               |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

10 MAY 2021 23:59

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:30

| 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"/>                                               |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

17 MAY 2021 23:59

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:30

| 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"/>                                               |



US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

24 MAY 2021 23:59

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:30

| 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"/>                                               |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

31 MAY 2021 23:59

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:30

| 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"/>                                               |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

07 JUN 2021 23:59

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:30

| 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"/>                                               |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

14 JUN 2021 23:59

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:30

| 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 <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"/>                                               |



US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

21 JUN 2021 23:59

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:30

| 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"/>                                               |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

28 JUN 2021 23:59

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:30

| 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"/>                                               |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

05 JUL 2021 23:59

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:30

| 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"/>                                               |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

12 JUL 2021 23:59

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:30

| 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"/>                                               |



US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

19 JUL 2021 23:59

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:30

| 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"/>                                               |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

26 JUL 2021 23:59

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:30

| 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"/>                                               |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

02 AUG 2021 23:59

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:30

**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 ☐ 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 ☐

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

09 AUG 2021 23:59

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:30

| 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 <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"/>                                               |



US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

Please contact your study clinic immediately. Click below to confirm that you have read this 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

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12 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

16 AUG 2021 23:59

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:30

| 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 <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"/>                                               |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

23 AUG 2021 23:59

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:30

| 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"/>                                               |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

30 AUG 2021 23:59

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:30

| 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 <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"/>                                               |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

06 SEP 2021 23:59

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:30

| 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"/>                                               |



US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

13 SEP 2021 23:59

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:30

| 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"/>                                               |

**US3532063**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

20 SEP 2021 23:59

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:30

| 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"/>                                               |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

27 SEP 2021 23:59

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:30

| 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"/>                                               |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

04 OCT 2021 23:59

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:30

| 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 <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"/>                                               |



US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

11 OCT 2021 23:59

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:30

| 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 <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"/>                                               |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

18 OCT 2021 23:59

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:30

| 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 <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"/>                                               |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

25 OCT 2021 23:59

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:30

| 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"/>                                               |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 2021 00:01

[Patient Cloud Close Date & Time](#)

01 NOV 2021 23:59

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:30

| 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 <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"/>                                               |



US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 2021 00:01

[Patient Cloud Close Date & Time](#)

08 NOV 2021 23:59

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:30

| 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"/>                                               |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 2021 00:01

[Patient Cloud Close Date & Time](#)

15 NOV 2021 23:59

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:30

| 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"/>                                               |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

22 NOV 2021 23:59

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:30

| 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"/>                                               |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 2021 00:01

[Patient Cloud Close Date & Time](#)

29 NOV 2021 23:59

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:30

| 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"/>                                               |



US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 2021 00:01

[Patient Cloud Close Date & Time](#)

06 DEC 2021 23:59

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:30

| 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"/>                                               |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 2021 00:01

[Patient Cloud Close Date & Time](#)

13 DEC 2021 23:59

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:30

| 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"/>                                               |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 2021 00:01

[Patient Cloud Close Date & Time](#)

20 DEC 2021 23:59

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:30

| 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"/>                                               |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 2021 00:01

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27 DEC 2021 23:59

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:30

| 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 <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"/>                                               |



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**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 ☐

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30 DEC 2021 00:01

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03 JAN 2022 23:59

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:30

| 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 <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"/>                                               |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

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

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

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10 JAN 2022 23:59

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:30

**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 ☐ 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 ☐

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

Please contact your study clinic immediately. Click below to confirm that you have read this 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

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13 JAN 2022 00:01

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17 JAN 2022 23:59

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:30

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 ☐

US3532063

**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

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24 JAN 2022 23:59

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:30

| 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"/>                                               |



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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

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27 JAN 2022 00:01

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31 JAN 2022 23:59

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:30

| 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 <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"/>                                               |

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**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

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03 FEB 2022 00:01

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07 FEB 2022 23:59

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:30

| 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"/>                                               |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 2022 00:01

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14 FEB 2022 23:59

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:30

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 ☐ 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 ☐

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

Please contact your study clinic immediately. Click below to confirm that you have read this 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

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17 FEB 2022 00:01

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21 FEB 2022 23:59

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:30

**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 ☐ 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 ☐



US3532063

**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

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24 FEB 2022 00:01

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28 FEB 2022 23:59

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:30

**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 ☐

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 2022 00:01

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07 MAR 2022 23:59

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:30

**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 ☐

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 2022 00:01

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14 MAR 2022 23:59

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:30

**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 ☐

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 MAR 2022 00:01

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21 MAR 2022 23:59

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:30

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 ☐



US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 2022 00:01

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28 MAR 2022 23:59

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:30

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 ☐

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 2022 00:01

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04 APR 2022 23:59

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:30

| 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"/>                                               |

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 2022 00:01

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11 APR 2022 23:59

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:30

| 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 <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"/>                                               |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 2022 00:01

[Patient Cloud Close Date & Time](#)

18 APR 2022 23:59

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:30

| 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"/>                                               |



US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 2022 00:01

[Patient Cloud Close Date & Time](#)

25 APR 2022 23:59

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:30

| 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"/>                                               |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 2022 00:01

[Patient Cloud Close Date & Time](#)

02 MAY 2022 23:59

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:30

| 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 <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"/>                                               |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 2022 00:01

[Patient Cloud Close Date & Time](#)

09 MAY 2022 23:59

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:30

| 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 <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"/>                                               |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 2022 00:01

[Patient Cloud Close Date & Time](#)

16 MAY 2022 23:59

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:30

| 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"/>                                               |



US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 2022 00:01

[Patient Cloud Close Date & Time](#)

23 MAY 2022 23:59

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:30

| 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"/>                                               |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 2022 00:01

[Patient Cloud Close Date & Time](#)

30 MAY 2022 23:59

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:30

| 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"/>                                               |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JUN 2022 23:59

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:30

**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 ☐

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JUN 2022 23:59

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:30

| 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 <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"/>                                               |



US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 2022 00:01

[Patient Cloud Close Date & Time](#)

20 JUN 2022 23:59

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:30

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 ☐

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 2022 00:01

[Patient Cloud Close Date & Time](#)

27 JUN 2022 23:59

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:30

| 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"/>                                               |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 2022 00:01

[Patient Cloud Close Date & Time](#)

04 JUL 2022 23:59

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:30

| 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"/>                                               |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 2022 00:01

[Patient Cloud Close Date & Time](#)

11 JUL 2022 23:59

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:30

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 ☐ 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 ☐



US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 2022 00:01

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18 JUL 2022 23:59

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:30

**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 ☐

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

Please contact your study clinic immediately. Click below to confirm that you have read this 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

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21 JUL 2022 00:01

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25 JUL 2022 23:59

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:30

| 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"/>                                               |

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

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**Generated On: 26 Nov 2020 09:35:30**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 2022 00:01

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01 AUG 2022 23:59

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:30

| 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"/>                                               |

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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

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04 AUG 2022 00:01

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08 AUG 2022 23:59

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:30

| 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 <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"/>                                               |



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

Date and time of submission

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11 AUG 2022 00:01

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15 AUG 2022 23:59

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Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:30

| 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"/>                                               |

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

**Form: Safety Follow Up Diary**

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

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18 AUG 2022 00:01

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22 AUG 2022 23:59

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:30

| 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"/>                                               |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

Please contact your study clinic immediately. Click below to confirm that you have read this 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

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25 AUG 2022 00:01

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29 AUG 2022 23:59

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:30

| 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"/>                                               |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

Please contact your study clinic immediately. Click below to confirm that you have read this 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

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01 SEP 2022 00:01

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05 SEP 2022 23:59

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:30

| 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"/>                                               |



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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 ☐

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08 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

12 SEP 2022 23:59

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:30

| 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"/>                                               |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 2022 00:01

[Patient Cloud Close Date & Time](#)

19 SEP 2022 23:59

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:30

| 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"/>                                               |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 2022 00:01

[Patient Cloud Close Date & Time](#)

26 SEP 2022 23:59

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:30

| 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"/>                                               |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 2022 00:01

[Patient Cloud Close Date & Time](#)

03 OCT 2022 23:59

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:30

| 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 <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"/>                                               |



US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 2022 00:01

[Patient Cloud Close Date & Time](#)

10 OCT 2022 23:59

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:30

| 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"/>                                               |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 2022 00:01

[Patient Cloud Close Date & Time](#)

17 OCT 2022 23:59

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:30

| 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 <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"/>                                               |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 2022 00:01

[Patient Cloud Close Date & Time](#)

24 OCT 2022 23:59

US3532063

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:35:30

Was Contact Attempted?

Yes ☒

No ☐

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

9 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3532063

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:35:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3532063

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:35:30

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*



US3532063

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:35:30

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3532063

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:35:30

|                                                  |                                                       |
|--------------------------------------------------|-------------------------------------------------------|
| Date of Contact                                  |                                                       |
| Time of Contact                                  |                                                       |
| Date and Time of Contact (derived)               |                                                       |
| Type of Contact                                  | Clinic Visit - Scheduled <input type="checkbox"/>     |
|                                                  | Clinical Visit - Unscheduled <input type="checkbox"/> |
|                                                  | Safety Call <input type="checkbox"/>                  |
|                                                  | Convalescent Tele-visit <input type="checkbox"/>      |
| Has the subject reported symptoms of SARS-COV-2? | Yes <input type="checkbox"/>                          |
|                                                  | No <input type="checkbox"/>                           |

US3532063

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 26 Nov 2020 09:35:30

---

Generate Next COVID-19 Assessment

Yes ☐

No ☐

---

US3532063

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 09:35:30

---

Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

---

US3532063

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:35:30

|                                                                |                                                                                                                                                                  |
|----------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| AEID                                                           | USA-US077-2020-MRNA-1273-P30<br>1000007                                                                                                                          |
| Adverse event                                                  | FRACTURED FEMUR                                                                                                                                                  |
| 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)                                       | 28 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 type="radio"/><br>Grade 3/Severe <input type="radio"/><br>Grade 4 <input checked="" 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 | True                                                                                                                                                             |
| Hospital Admission Date (dd MMM yyyy)                          | 28 OCT 2020                                                                                                                                                      |
| Hospital Discharge Date (dd MMM yyyy)                          | 01 NOV 2020                                                                                                                                                      |
| Admitted to ICU?                                               | Yes <input type="radio"/><br>No <input checked="" type="radio"/><br>Unknown <input type="radio"/>                                                                |
| Number of Days in ICU                                          |                                                                                                                                                                  |

v6.020 DTW (1102)

340 of 1874

US3532063

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:35:30

|                                                                              |                                                                                                                                                                                                                                                                                 |
|------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Persistent or significant disability or incapacity                           | False                                                                                                                                                                                                                                                                           |
| 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 <input type="radio"/><br>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                                                        | True                                                                                                                                                                                                                                                                            |
| 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: |                                                                                                                                                                                                                                                                                 |
| Narrative                                                                    |                                                                                                                                                                                                                                                                                 |

US3532063

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:35:30

---

WHILE OUT OF TOWN,  
SUBJECT FELL AND  
FRACTURED L FEMUR.  
HOSPITALIZED AND  
SURGICALLY REPAIRED. HAS  
BEEN DISCHARGED FOR  
REHAB AND IS STILL OUT OF  
STATE. WILL OBTAIN  
HOSPITAL RECORDS

RECORDS PROVIDED 11-17-20

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|                                                            |   |
|------------------------------------------------------------|---|
| 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)       | 0 |

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US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination Summary**

**Generated On: 26 Nov 2020 09:35:30**

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Were any prior/concomitant medications and/or vaccinations taken?

Yes ☒

No ☐

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**If Yes, please complete Prior/Concomitant Medication and Vaccination form.**

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

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|                                |                                                                                                                                                                                                                                                                                                                                                                                                                          |
|--------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Name of Medication             | OMEGA 3                                                                                                                                                                                                                                                                                                                                                                                                                  |
| Prophylaxis                    | Yes <input checked="" type="radio"/><br>No <input type="radio"/>                                                                                                                                                                                                                                                                                                                                                         |
| Indication                     | HEALTH                                                                                                                                                                                                                                                                                                                                                                                                                   |
| Dose per administration        | 1200                                                                                                                                                                                                                                                                                                                                                                                                                     |
| 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 (1)

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|                                                                   |                          |                                      |
|-------------------------------------------------------------------|--------------------------|--------------------------------------|
|                                                                   | 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) <input type="text"/>                     |                          |                                      |
| <hr/>                                                             |                          |                                      |
| Start date completely unknown                                     |                          | True                                 |
| <hr/>                                                             |                          |                                      |
| 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                                    |
| <hr/>                                                             |                          |                                      |
| Interval Dosage Unit Number (derived)                             |                          | 1                                    |
| <hr/>                                                             |                          |                                      |
| Interval Dosage Definition (derived)                              |                          | 802 <input type="radio"/>            |
|                                                                   |                          | 803 <input type="radio"/>            |
|                                                                   |                          | 804 <input checked="" type="radio"/> |
| <hr/>                                                             |                          |                                      |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

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|                                |                                                                                                                                                                                                                                                                                                                                                                                                                          |
|--------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Name of Medication             | CALCIUM                                                                                                                                                                                                                                                                                                                                                                                                                  |
| Prophylaxis                    | Yes <input checked="" type="radio"/><br>No <input type="radio"/>                                                                                                                                                                                                                                                                                                                                                         |
| Indication                     | HEALTH                                                                                                                                                                                                                                                                                                                                                                                                                   |
| 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 checked="" 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 (2)

Generated On: 26 Nov 2020 09:35:30

|                                                                   |                          |                                      |
|-------------------------------------------------------------------|--------------------------|--------------------------------------|
|                                                                   | 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) <input type="text"/>                     |                          |                                      |
| <hr/>                                                             |                          |                                      |
| Start date completely unknown                                     |                          | True                                 |
| <hr/>                                                             |                          |                                      |
| 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)                                  |                          | 3                                    |
| <hr/>                                                             |                          |                                      |
| Interval Dosage Unit Number (derived)                             |                          | 1                                    |
| <hr/>                                                             |                          |                                      |
| Interval Dosage Definition (derived)                              |                          | 802 <input type="radio"/>            |
|                                                                   |                          | 803 <input type="radio"/>            |
|                                                                   |                          | 804 <input checked="" type="radio"/> |
| <hr/>                                                             |                          |                                      |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

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|                                      |                                                                                                                                                                                                                                                                                                                                                                                                                          |
|--------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Name of Medication                   | TUMERIC                                                                                                                                                                                                                                                                                                                                                                                                                  |
| Prophylaxis                          | Yes <input checked="" type="radio"/><br>No <input type="radio"/>                                                                                                                                                                                                                                                                                                                                                         |
| Indication                           | HEALTH                                                                                                                                                                                                                                                                                                                                                                                                                   |
| 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 checked="" 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 (3)

Generated On: 26 Nov 2020 09:35:30

|                                                                   |                          |                                      |
|-------------------------------------------------------------------|--------------------------|--------------------------------------|
|                                                                   | 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) <input type="text"/>                     |                          |                                      |
| <hr/>                                                             |                          |                                      |
| Start date completely unknown                                     |                          | True                                 |
| 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)                                  |                          | 2                                    |
| Interval Dosage Unit Number (derived)                             |                          | 1                                    |
| Interval Dosage Definition (derived)                              |                          | 802 <input type="radio"/>            |
|                                                                   |                          | 803 <input type="radio"/>            |
|                                                                   |                          | 804 <input checked="" type="radio"/> |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

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|                                |                                                                                                                                                                                                                                                                                                                                                                                                                          |
|--------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Name of Medication             | MULTI VITAMIN                                                                                                                                                                                                                                                                                                                                                                                                            |
| Prophylaxis                    | Yes <input checked="" type="radio"/><br>No <input type="radio"/>                                                                                                                                                                                                                                                                                                                                                         |
| Indication                     | HEALTH                                                                                                                                                                                                                                                                                                                                                                                                                   |
| Dose per administration        | 1                                                                                                                                                                                                                                                                                                                                                                                                                        |
| 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 checked="" 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 (4)

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|                                                                   |                          |                                      |
|-------------------------------------------------------------------|--------------------------|--------------------------------------|
|                                                                   | 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) <input type="text"/>                     |                          |                                      |
| <hr/>                                                             |                          |                                      |
| Start date completely unknown                                     |                          | True                                 |
| 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"/> |



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

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|                                |                                                                                                                                                                                                                                                                                                                                                                                                                          |
|--------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Name of Medication             | SUPER B VITAMIN                                                                                                                                                                                                                                                                                                                                                                                                          |
| Prophylaxis                    | Yes <input checked="" type="radio"/><br>No <input type="radio"/>                                                                                                                                                                                                                                                                                                                                                         |
| Indication                     | HEALTH                                                                                                                                                                                                                                                                                                                                                                                                                   |
| Dose per administration        | 1                                                                                                                                                                                                                                                                                                                                                                                                                        |
| 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 checked="" 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 (5)

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|                                                                   |                          |                                      |
|-------------------------------------------------------------------|--------------------------|--------------------------------------|
|                                                                   | 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) <input type="text"/>                     |                          |                                      |
| <hr/>                                                             |                          |                                      |
| Start date completely unknown                                     |                          | True                                 |
| <hr/>                                                             |                          |                                      |
| 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                                    |
| <hr/>                                                             |                          |                                      |
| Interval Dosage Unit Number (derived)                             |                          | 1                                    |
| <hr/>                                                             |                          |                                      |
| Interval Dosage Definition (derived)                              |                          | 802 <input type="radio"/>            |
|                                                                   |                          | 803 <input type="radio"/>            |
|                                                                   |                          | 804 <input checked="" type="radio"/> |
| <hr/>                                                             |                          |                                      |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:35:30

|                                |                                                                                                                                                                                                                                                                                                                                                                                                                          |
|--------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Name of Medication             | VITAMIN D3                                                                                                                                                                                                                                                                                                                                                                                                               |
| Prophylaxis                    | Yes <input checked="" type="radio"/><br>No <input type="radio"/>                                                                                                                                                                                                                                                                                                                                                         |
| Indication                     | HEALTH                                                                                                                                                                                                                                                                                                                                                                                                                   |
| Dose per administration        | 5000                                                                                                                                                                                                                                                                                                                                                                                                                     |
| Dose unit                      | mg <input type="radio"/><br>ug <input type="radio"/><br>mL <input type="radio"/><br>g <input type="radio"/><br>IU <input checked="" 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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Form: Prior/Concomitant Medication and Vaccination (6)

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|                                                                   |                          |                                      |
|-------------------------------------------------------------------|--------------------------|--------------------------------------|
|                                                                   | 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) <input type="text"/>                     |                          |                                      |
| <hr/>                                                             |                          |                                      |
| Start date completely unknown                                     |                          | True                                 |
| 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"/> |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

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|                                      |                                                                                                                                                                                                                                                                                                                                                                                                                          |
|--------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Name of Medication                   | VITAMIN E                                                                                                                                                                                                                                                                                                                                                                                                                |
| Prophylaxis                          | Yes <input checked="" type="radio"/><br>No <input type="radio"/>                                                                                                                                                                                                                                                                                                                                                         |
| Indication                           | HEALTH                                                                                                                                                                                                                                                                                                                                                                                                                   |
| Dose per administration              | 400                                                                                                                                                                                                                                                                                                                                                                                                                      |
| Dose unit                            | mg <input type="radio"/><br>ug <input type="radio"/><br>mL <input type="radio"/><br>g <input type="radio"/><br>IU <input checked="" 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 (7)

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|                                                                   |                          |                                      |
|-------------------------------------------------------------------|--------------------------|--------------------------------------|
|                                                                   | 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) <input type="text"/>                     |                          |                                      |
| <hr/>                                                             |                          |                                      |
| Start date completely unknown                                     |                          | True                                 |
| 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"/> |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

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|                                |                                                                                                                                                                                                                                                                                                                                                                                                                          |
|--------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Name of Medication             | GLUCOSAMINE CHONDROITIN                                                                                                                                                                                                                                                                                                                                                                                                  |
| Prophylaxis                    | Yes <input checked="" type="radio"/><br>No <input type="radio"/>                                                                                                                                                                                                                                                                                                                                                         |
| Indication                     | HEALTH                                                                                                                                                                                                                                                                                                                                                                                                                   |
| Dose per administration        | 500                                                                                                                                                                                                                                                                                                                                                                                                                      |
| 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 checked="" 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 (8)

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|                                                                   |                          |                                      |
|-------------------------------------------------------------------|--------------------------|--------------------------------------|
|                                                                   | 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) <input type="text"/>                     |                          |                                      |
| <hr/>                                                             |                          |                                      |
| Start date completely unknown                                     |                          | True                                 |
| 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)                                  |                          | 2                                    |
| Interval Dosage Unit Number (derived)                             |                          | 1                                    |
| Interval Dosage Definition (derived)                              |                          | 802 <input type="radio"/>            |
|                                                                   |                          | 803 <input type="radio"/>            |
|                                                                   |                          | 804 <input checked="" type="radio"/> |



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

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|                                |                                                |
|--------------------------------|------------------------------------------------|
| Name of Medication             | FLU AD                                         |
| Prophylaxis                    | Yes <input checked="" type="radio"/>           |
|                                | No <input type="radio"/>                       |
| Indication                     | ANNUAL FLU VACCINE                             |
| Dose per administration        | 0.5                                            |
| Dose unit                      | mg <input checked="" type="radio"/>            |
|                                | ug <input type="radio"/>                       |
|                                | mL <input type="radio"/>                       |
|                                | g <input type="radio"/>                        |
|                                | IU <input type="radio"/>                       |
|                                | tablet <input type="radio"/>                   |
|                                | capsule <input type="radio"/>                  |
|                                | puff <input type="radio"/>                     |
|                                | Other <input type="radio"/>                    |
| If dose unit is Other, specify |                                                |
| Frequency                      | once daily <input type="radio"/>               |
|                                | twice daily <input type="radio"/>              |
|                                | three times daily <input type="radio"/>        |
|                                | four times daily <input type="radio"/>         |
|                                | every other day <input type="radio"/>          |
|                                | every week <input type="radio"/>               |
|                                | every month <input type="radio"/>              |
|                                | as needed <input type="radio"/>                |
|                                | once <input checked="" type="radio"/>          |
|                                | unknown <input type="radio"/>                  |
|                                | other <input type="radio"/>                    |
| If frequency is Other, specify |                                                |
| Route of administration        | Oral <input type="radio"/>                     |
|                                | Topical <input type="radio"/>                  |
|                                | Subcutaneous <input type="radio"/>             |
|                                | Transdermal <input type="radio"/>              |
|                                | Intraocular <input type="radio"/>              |
|                                | Intramuscular <input checked="" type="radio"/> |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

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|                                                                   |                          |                                     |
|-------------------------------------------------------------------|--------------------------|-------------------------------------|
|                                                                   | 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)                                          |                          | 7 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)                            |                          | 7 OCT 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"/>            |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

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|                                |                                                                                                                                                                                                                                                                                                                                                                                                                          |
|--------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Name of Medication             | ELIQUIS                                                                                                                                                                                                                                                                                                                                                                                                                  |
| Prophylaxis                    | Yes <input checked="" type="radio"/><br>No <input type="radio"/>                                                                                                                                                                                                                                                                                                                                                         |
| Indication                     | POST SURGICAL DVT<br>PROPHYLAXIS                                                                                                                                                                                                                                                                                                                                                                                         |
| Dose per administration        | 2.5                                                                                                                                                                                                                                                                                                                                                                                                                      |
| 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 checked="" 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"/>                                                                                                                                                                                                                                   |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

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|                                                    |                          |                                  |
|----------------------------------------------------|--------------------------|----------------------------------|
|                                                    | 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"/>            |
| <hr/>                                              |                          |                                  |
| If route of administration is Other, specify <hr/> |                          |                                  |
| Start date (dd MMM yyyy)                           | 01 NOV 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"/> |
| Separate Dosage Number (derived)                   | 2                        |                                  |
| Interval Dosage Unit Number (derived)              | 1                        |                                  |
| Interval Dosage Definition (derived)               | 802                      | <input type="radio"/>            |
|                                                    | 803                      | <input type="radio"/>            |
|                                                    | 804                      | <input checked="" type="radio"/> |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

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|                                |                                                                                                                                                                                                                                                                                                                                                                                                                          |
|--------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Name of Medication             | FLEXERIL                                                                                                                                                                                                                                                                                                                                                                                                                 |
| Prophylaxis                    | Yes <input type="radio"/><br>No <input checked="" type="radio"/>                                                                                                                                                                                                                                                                                                                                                         |
| Indication                     | POST SURGICAL MUSCLE<br>SPASMS                                                                                                                                                                                                                                                                                                                                                                                           |
| 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 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)

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|                                                    |                          |                                  |
|----------------------------------------------------|--------------------------|----------------------------------|
|                                                    | 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 <hr/> |                          |                                  |
| Start date (dd MMM yyyy)                           |                          | 01 NOV 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"/>            |

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|                                |                                                                                                                                                                                                                                                                                                                                                                                                                          |
|--------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Name of Medication             | COLACE                                                                                                                                                                                                                                                                                                                                                                                                                   |
| Prophylaxis                    | Yes <input checked="" type="radio"/><br>No <input type="radio"/>                                                                                                                                                                                                                                                                                                                                                         |
| Indication                     | POST SURGICAL<br>CONSTIPATION                                                                                                                                                                                                                                                                                                                                                                                            |
| Dose per administration        | 100                                                                                                                                                                                                                                                                                                                                                                                                                      |
| 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"/>                                                                                                                                                                                                                                   |

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Form: Prior/Concomitant Medication and Vaccination (12)

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|                                                    |                          |                                  |
|----------------------------------------------------|--------------------------|----------------------------------|
|                                                    | 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 <hr/> |                          |                                  |
| Start date (dd MMM yyyy)                           | 01 NOV 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"/>            |



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|                                |                                                                                                                                                                                                                                                                                                                                                                                                                          |
|--------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Name of Medication             | ZOFRAN                                                                                                                                                                                                                                                                                                                                                                                                                   |
| Prophylaxis                    | Yes <input checked="" type="radio"/><br>No <input type="radio"/>                                                                                                                                                                                                                                                                                                                                                         |
| Indication                     | POST SURGICAL NAUSEA                                                                                                                                                                                                                                                                                                                                                                                                     |
| Dose per administration        | 4                                                                                                                                                                                                                                                                                                                                                                                                                        |
| 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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Form: Prior/Concomitant Medication and Vaccination (13)

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|                                                                   |                          |                                  |
|-------------------------------------------------------------------|--------------------------|----------------------------------|
|                                                                   | 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)                                          |                          | 01 NOV 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"/>            |

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:35:30

|                                |                                                                                                                                                                                                                                                                                                                                                                                                                          |
|--------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Name of Medication             | PERCOSET                                                                                                                                                                                                                                                                                                                                                                                                                 |
| Prophylaxis                    | Yes <input type="radio"/><br>No <input checked="" type="radio"/>                                                                                                                                                                                                                                                                                                                                                         |
| Indication                     | POSTSURGICAL PAIN                                                                                                                                                                                                                                                                                                                                                                                                        |
| Dose per administration        | 7.5/325                                                                                                                                                                                                                                                                                                                                                                                                                  |
| 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"/>                                                                                                                                                                                            |

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:35:30

|                                                                   |                          |                                  |
|-------------------------------------------------------------------|--------------------------|----------------------------------|
|                                                                   | 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)                                          |                          | 01 NOV 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"/>            |

US3532063

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures Summary**

**Generated On: 26 Nov 2020 09:35:30**

[Were any concomitant procedures performed?](#)

Yes ☒

No ☐

**If yes, please complete Concomitant Procedures form.**

US3532063

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures**

**Generated On: 26 Nov 2020 09:35:30**

| Procedure/Surgery date ( <i>dd MMM<br/>yyyy</i> ) | Procedure/Surgery                     | Indication    | If indication is Other, specify |
|---------------------------------------------------|---------------------------------------|---------------|---------------------------------|
| 29 OCT 2020                                       | SURGICAL REPAIR OF<br>FRACTURED FEMUR | Adverse Event |                                 |

US3532063

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 09:35:30

Date of dosing discontinuation (dd MMM yyyy)

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

US3532063

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 09:35:30

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 ☐



US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:30

|                                                                |                                                               |
|----------------------------------------------------------------|---------------------------------------------------------------|
| SAEID                                                          | USA-US077-2020-MRNA-1273-P301000007                           |
| 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 checked="" type="radio"/> No <input 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 type="radio"/> No <input checked="" type="radio"/> |
| Investigator's First Name                                      | EVAN                                                          |
| Investigator's Last Name                                       | ANDERSON                                                      |
| Site Address: Street                                           | 2015 UPPERGATE DRIVE                                          |
| Site Address: City                                             | ATLANTA                                                       |
| Site Address: State                                            | GA                                                            |
| Site Address: Postal Code                                      | 30323                                                         |
| Investigator Country                                           | US                                                            |
| E2B Transmit Flag (Derived/Hidden)                             | 3                                                             |

US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 09:35:30

|                                                                                                                                                                                               |                                                               |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------|
| SAEID                                                                                                                                                                                         | USA-US077-2020-MRNA-1273-P301000007                           |
| 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 checked="" type="radio"/> No <input 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 type="radio"/> No <input checked="" type="radio"/> |
| Investigator's First Name                                                                                                                                                                     | EVAN                                                          |
| Investigator's Last Name                                                                                                                                                                      | ANDERSON                                                      |
| Site Address: Street                                                                                                                                                                          | 2015 UPPERGATE DRIVE                                          |
| Site Address: City                                                                                                                                                                            | ATLANTA                                                       |
| Site Address: State                                                                                                                                                                           | GA                                                            |
| Site Address: Postal Code                                                                                                                                                                     | 30323                                                         |
| Investigator Country                                                                                                                                                                          | US                                                            |
| E2B Transmit Flag (Derived/Hidden)                                                                                                                                                            | 3                                                             |
| Date of submission (Pre-filled from custom function)                                                                                                                                          | 04/NOV/2020 12:44                                             |
| 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                                                          |

US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 09:35:30

|                                                                                                                                                                                               |                                                                  |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------|
| SAEID                                                                                                                                                                                         | USA-US077-2020-MRNA-1273-P301000007                              |
| 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 checked="" type="radio"/><br>No <input 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 type="radio"/><br>No <input checked="" type="radio"/> |
| Investigator's First Name                                                                                                                                                                     | EVAN                                                             |
| Investigator's Last Name                                                                                                                                                                      | ANDERSON                                                         |
| Site Address: Street                                                                                                                                                                          | 2015 UPPERGATE DRIVE                                             |
| Site Address: City                                                                                                                                                                            | ATLANTA                                                          |
| Site Address: State                                                                                                                                                                           | GA                                                               |
| Site Address: Postal Code                                                                                                                                                                     | 30323                                                            |
| Investigator Country                                                                                                                                                                          | US                                                               |
| E2B Transmit Flag (Derived/Hidden)                                                                                                                                                            | 3                                                                |
| Date of submission (Pre-filled from custom function)                                                                                                                                          | 17/NOV/2020 09:43                                                |
| 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                                                             |

US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 09:35:30

|                                                                                                                                                                                               |                                                               |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------|
| SAEID                                                                                                                                                                                         | USA-US077-2020-MRNA-1273-P301000007                           |
| 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 checked="" type="radio"/> No <input 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 type="radio"/> No <input checked="" type="radio"/> |
| Investigator's First Name                                                                                                                                                                     | EVAN                                                          |
| Investigator's Last Name                                                                                                                                                                      | ANDERSON                                                      |
| Site Address: Street                                                                                                                                                                          | 2015 UPPERGATE DRIVE                                          |
| Site Address: City                                                                                                                                                                            | ATLANTA                                                       |
| Site Address: State                                                                                                                                                                           | GA                                                            |
| Site Address: Postal Code                                                                                                                                                                     | 30323                                                         |
| Investigator Country                                                                                                                                                                          | US                                                            |
| E2B Transmit Flag (Derived/Hidden)                                                                                                                                                            | 3                                                             |
| Date of submission (Pre-filled from custom function)                                                                                                                                          | 18/NOV/2020 08:46                                             |
| 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

US3532063 (Prod: Children's Healthcare of Atlanta)

US3532063

**Form: Participant Creation**

**Generated On: 26 Nov 2020 09:35:30**

[Participant ID](#)

| Audit                    | User                                            | Time (GMT)           |
|--------------------------|-------------------------------------------------|----------------------|
| User entered 'US3532063' | RWS_ENDPOINT<br>ENDPOINT (b) (4)<br><div></div> | 18 Aug 2020 17:29:48 |

US3532063

**Folder: Screening**

**Form: Visit Date**

**Generated On: 26 Nov 2020 09:35:30**

[Was this visit performed?](#)

| Audit                  | User                              | Time (GMT)           |
|------------------------|-----------------------------------|----------------------|
| User entered 'Yes (Y)' | Kathy Stephens (b) (4)<br>(b) (4) | 18 Aug 2020 17:51:34 |

US3532063

**Folder: Screening**

**Form: Visit Date**

**Generated On: 26 Nov 2020 09:35:30**

[Visit date \(dd MMM yyyy\)](#)

| Audit                      | User                                            | Time (GMT)           |
|----------------------------|-------------------------------------------------|----------------------|
| User entered '18 AUG 2020' | RWS_ENDPOINT<br>ENDPOINT (b) (4)<br><div></div> | 18 Aug 2020 17:29:49 |



US3532063

**Folder: Screening**

**Form: Visit Date**

**Generated On: 26 Nov 2020 09:35:30**

[Was visit performed at the participant's home or at the clinic?](#)

| Audit                          | User                              | Time (GMT)           |
|--------------------------------|-----------------------------------|----------------------|
| User entered 'Clinic (Clinic)' | Kathy Stephens (b) (4)<br>(b) (4) | 18 Aug 2020 17:51:34 |

US3532063

**Folder: Screening**

**Form: Visit Date**

**Generated On: 26 Nov 2020 09:35:30**

[Folder OID](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'SCRN' | System | 18 Aug 2020 17:51:34 |

US3532063

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 09:35:30**

[Date of Birth \(MMM yyyy\)](#)

| Audit                      | User                                           | Time (GMT)           |
|----------------------------|------------------------------------------------|----------------------|
| User entered (b) (6) 1949' | RWS_ENDPOINT<br>ENDPOINT (b) (4)<br>[REDACTED] | 18 Aug 2020 17:29:50 |

US3532063

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:35:30

[Age](#)

| Audit             | User                              | Time (GMT)           |
|-------------------|-----------------------------------|----------------------|
| User entered '70' | Kathy Stephens (b) (4)<br>(b) (4) | 18 Aug 2020 17:52:00 |

US3532063

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 09:35:30**

[Age Units](#)

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| User entered 'YEARS' | System | 18 Aug 2020 17:52:00 |

US3532063

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 09:35:30**

[Age \(Derived\)](#)

| Audit             | User   | Time (GMT)           |
|-------------------|--------|----------------------|
| User entered '70' | System | 18 Aug 2020 17:52:19 |

US3532063

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 09:35:30**

[Sex](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| User entered 'Female (F)' | Kathy Stephens (b) (4)<br>(b) (4) | 18 Aug 2020 17:52:00 |

US3532063

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 09:35:30**

[Ethnicity](#)

| Audit                                                          | User                              | Time (GMT)           |
|----------------------------------------------------------------|-----------------------------------|----------------------|
| User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)' | Kathy Stephens (b) (4)<br>(b) (4) | 18 Aug 2020 17:52:00 |



US3532063

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:35:30

[White](#)

| Audit            | User                              | Time (GMT)           |
|------------------|-----------------------------------|----------------------|
| User entered '1' | Kathy Stephens (b) (4)<br>(b) (4) | 18 Aug 2020 17:52:00 |

US3532063

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:35:30

[Black](#)

| Audit            | User                              | Time (GMT)           |
|------------------|-----------------------------------|----------------------|
| User entered '0' | Kathy Stephens (b) (4)<br>(b) (4) | 18 Aug 2020 17:52:00 |

US3532063

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:35:30

[Asian](#)

| Audit            | User                              | Time (GMT)           |
|------------------|-----------------------------------|----------------------|
| User entered '0' | Kathy Stephens (b) (4)<br>(b) (4) | 18 Aug 2020 17:52:00 |

US3532063

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 09:35:30**

[American Indian or Alaska Native](#)

| Audit            | User                              | Time (GMT)           |
|------------------|-----------------------------------|----------------------|
| User entered '0' | Kathy Stephens (b) (4)<br>(b) (4) | 18 Aug 2020 17:52:00 |

US3532063

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 09:35:30**

[Native Hawaiian or other Pacific Islander](#)

| Audit            | User                              | Time (GMT)           |
|------------------|-----------------------------------|----------------------|
| User entered '0' | Kathy Stephens (b) (4)<br>(b) (4) | 18 Aug 2020 17:52:00 |

US3532063

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:35:30

[Other](#)

| Audit            | User                              | Time (GMT)           |
|------------------|-----------------------------------|----------------------|
| User entered '0' | Kathy Stephens (b) (4)<br>(b) (4) | 18 Aug 2020 17:52:00 |

US3532063

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 09:35:30**

[If race is Other, specify](#)

| Audit               | User                              | Time (GMT)           |
|---------------------|-----------------------------------|----------------------|
| User entered empty. | Kathy Stephens (b) (4)<br>(b) (4) | 18 Aug 2020 17:52:00 |

US3532063

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 09:35:30**

[Unknown](#)

| Audit            | User                              | Time (GMT)           |
|------------------|-----------------------------------|----------------------|
| User entered '0' | Kathy Stephens (b) (4)<br>(b) (4) | 18 Aug 2020 17:52:00 |



US3532063

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:35:30

[Not reported](#)

| Audit            | User                              | Time (GMT)           |
|------------------|-----------------------------------|----------------------|
| User entered '0' | Kathy Stephens (b) (4)<br>(b) (4) | 18 Aug 2020 17:52:00 |

US3532063

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 09:35:30**

[Date of Informed Consent \(dd MMM yyyy\)](#)

| Audit                      | User                              | Time (GMT)           |
|----------------------------|-----------------------------------|----------------------|
| User entered '18 Aug 2020' | Kathy Stephens (b) (4)<br>(b) (4) | 18 Aug 2020 17:52:19 |

US3532063

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 09:35:30**

[Month and Year of Informed Consent \(derived\)](#)

| Audit                   | User   | Time (GMT)           |
|-------------------------|--------|----------------------|
| User entered 'Aug 2020' | System | 18 Aug 2020 17:52:19 |

US3532063

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 09:35:30**

[Year of Informed Consent \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '2020' | System | 18 Aug 2020 17:52:19 |

US3532063

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 09:35:30**

[Protocol Version](#)

| Audit                          | User                              | Time (GMT)           |
|--------------------------------|-----------------------------------|----------------------|
| User entered 'Amendment 2 (2)' | Kathy Stephens (b) (4)<br>(b) (4) | 18 Aug 2020 17:52:19 |

US3532063

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 09:35:30**

[Was participant enrolled in the study?](#)

| Audit                  | User                              | Time (GMT)           |
|------------------------|-----------------------------------|----------------------|
| User entered 'Yes (Y)' | Kathy Stephens (b) (4)<br>(b) (4) | 18 Aug 2020 17:52:19 |

US3532063

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 09:35:30**

[If No, indicate reason for screen fail](#)

| Audit               | User                              | Time (GMT)           |
|---------------------|-----------------------------------|----------------------|
| User entered empty. | Kathy Stephens (b) (4)<br>(b) (4) | 18 Aug 2020 17:52:19 |

US3532063

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 09:35:30**

If reason for screen fail is Other, specify

| Audit               | User                              | Time (GMT)           |
|---------------------|-----------------------------------|----------------------|
| User entered empty. | Kathy Stephens (b) (4)<br>(b) (4) | 18 Aug 2020 17:52:19 |



US3532063

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 09:35:30**

[Was this participant screened previously?](#)

| Audit                 | User                              | Time (GMT)           |
|-----------------------|-----------------------------------|----------------------|
| User entered 'No (N)' | Kathy Stephens (b) (4)<br>(b) (4) | 18 Aug 2020 17:52:19 |

US3532063

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 09:35:30**

[If Yes, previous participant number](#)

| Audit               | User                                           | Time (GMT)           |
|---------------------|------------------------------------------------|----------------------|
| User entered empty. | RWS_ENDPOINT<br>ENDPOINT (b) (4)<br>[REDACTED] | 18 Aug 2020 17:29:49 |

US3532063

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 09:35:30**

[Enrollment Trigger](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 18 Aug 2020 18:35:01 |

US3532063

**Folder: Screening**

**Form: Inclusion/Exclusion Criteria Summary**

**Generated On: 26 Nov 2020 09:35:30**

[Did the participant meet all eligibility criteria?](#)

| Audit                  | User                              | Time (GMT)           |
|------------------------|-----------------------------------|----------------------|
| User entered 'Yes (Y)' | Kathy Stephens (b) (4)<br>(b) (4) | 18 Aug 2020 18:35:01 |

US3532063

**Folder: Screening**

**Form: Medical History Summary**

**Generated On: 26 Nov 2020 09:35:30**

[Were any significant conditions reported?](#)

| Audit                  | User                              | Time (GMT)           |
|------------------------|-----------------------------------|----------------------|
| User entered 'Yes (Y)' | Kathy Stephens (b) (4)<br>(b) (4) | 18 Aug 2020 18:35:10 |

US3532063

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:35:30

[Condition](#)

| Audit                                                                                                                                                                                          | User                              | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------|----------------------|
| User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Osteoarthritis - version MedDRA\\23.0. | Coder Import (b) (4)<br>(b) (4)   | 23 Aug 2020 05:43:33 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.                                                                                                        | Coder Import (b) (4)<br>(b) (4)   | 23 Aug 2020 05:43:33 |
| Data point term sent to Coder                                                                                                                                                                  | System                            | 22 Aug 2020 18:24:52 |
| User entered 'OSTEOARTHRITIS'                                                                                                                                                                  | Kathy Stephens (b) (4)<br>(b) (4) | 22 Aug 2020 18:23:53 |
| Neck and Legs' reason for change: Data Entry Error                                                                                                                                             |                                   |                      |
| Data point term sent to Coder                                                                                                                                                                  | System                            | 22 Aug 2020 18:22:49 |
| User entered 'Osteoarthritis'                                                                                                                                                                  | Kathy Stephens (b) (4)<br>(b) (4) | 22 Aug 2020 18:22:34 |

US3532063

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 09:35:30**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                              | Time (GMT)           |
|----------------------------|-----------------------------------|----------------------|
| User entered 'un UNK 2000' | Kathy Stephens (b) (4)<br>(b) (4) | 22 Aug 2020 18:22:34 |

US3532063

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 09:35:30**

[Start date completely unknown](#)

| Audit            | User                              | Time (GMT)           |
|------------------|-----------------------------------|----------------------|
| User entered '0' | Kathy Stephens (b) (4)<br>(b) (4) | 22 Aug 2020 18:22:34 |



US3532063

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 09:35:30**

[Condition ongoing at study entry](#)

| Audit                  | User                              | Time (GMT)           |
|------------------------|-----------------------------------|----------------------|
| User entered 'Yes (Y)' | Kathy Stephens (b) (4)<br>(b) (4) | 22 Aug 2020 18:22:34 |

US3532063

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 09:35:30**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

| Audit               | User                              | Time (GMT)           |
|---------------------|-----------------------------------|----------------------|
| User entered empty. | Kathy Stephens (b) (4)<br>(b) (4) | 22 Aug 2020 18:22:34 |

US3532063

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 09:35:30**

[Stop date completely unknown](#)

| Audit            | User                              | Time (GMT)           |
|------------------|-----------------------------------|----------------------|
| User entered '0' | Kathy Stephens (b) (4)<br>(b) (4) | 22 Aug 2020 18:22:34 |

US3532063

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 09:35:30**

[Start Month and Year \(derived\)](#)

| Audit                   | User   | Time (GMT)           |
|-------------------------|--------|----------------------|
| User entered 'Jan 2000' | System | 22 Aug 2020 18:22:34 |

US3532063

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 09:35:30**

[Start Year \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '2000' | System | 22 Aug 2020 18:22:34 |

US3532063

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 09:35:30**

[Stop Month and Year \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 22 Aug 2020 18:22:34 |

US3532063

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 09:35:30**

[Stop Year \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 22 Aug 2020 18:22:34 |

US3532063

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:35:30

[Condition](#)

| Audit                                                                                                                                                                                                      | User                              | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------|----------------------|
| User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Synovial and bursal disorders, HLT: Synovial disorders, PT: Synovial cyst, LLT: Ganglion cyst - version MedDRA\\23.0. | Coder Import (b) (4)<br>(b) (4)   | 22 Aug 2020 18:24:23 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.                                                                                                               | Coder Import (b) (4)<br>(b) (4)   | 22 Aug 2020 18:24:23 |
| Data point term sent to Coder                                                                                                                                                                              | System                            | 22 Aug 2020 18:23:51 |
| User entered 'ganglion cyst'                                                                                                                                                                               | Kathy Stephens (b) (4)<br>(b) (4) | 22 Aug 2020 18:23:16 |



US3532063

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 09:35:30**

[Start date \(dd MMM yyyy\)](#)

| Audit               | User                              | Time (GMT)           |
|---------------------|-----------------------------------|----------------------|
| User entered empty. | Kathy Stephens (b) (4)<br>(b) (4) | 22 Aug 2020 18:23:16 |

US3532063

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 09:35:30**

[Start date completely unknown](#)

| Audit            | User                              | Time (GMT)           |
|------------------|-----------------------------------|----------------------|
| User entered '1' | Kathy Stephens (b) (4)<br>(b) (4) | 22 Aug 2020 18:23:16 |

US3532063

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 09:35:30**

[Condition ongoing at study entry](#)

| Audit                 | User                              | Time (GMT)           |
|-----------------------|-----------------------------------|----------------------|
| User entered 'No (N)' | Kathy Stephens (b) (4)<br>(b) (4) | 22 Aug 2020 18:23:16 |

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**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 09:35:30**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

| Audit                      | User                              | Time (GMT)           |
|----------------------------|-----------------------------------|----------------------|
| User entered 'un UNK 1978' | Kathy Stephens (b) (4)<br>(b) (4) | 22 Aug 2020 18:23:16 |

US3532063

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 09:35:30**

[Stop date completely unknown](#)

| Audit            | User                              | Time (GMT)           |
|------------------|-----------------------------------|----------------------|
| User entered '0' | Kathy Stephens (b) (4)<br>(b) (4) | 22 Aug 2020 18:23:16 |

US3532063

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 09:35:30**

[Start Month and Year \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 22 Aug 2020 18:23:16 |

US3532063

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 09:35:30**

[Start Year \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 22 Aug 2020 18:23:16 |

US3532063

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 09:35:30**

[Stop Month and Year \(derived\)](#)

| Audit                   | User   | Time (GMT)           |
|-------------------------|--------|----------------------|
| User entered 'Jan 1978' | System | 22 Aug 2020 18:23:16 |



US3532063

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 09:35:30**

[Stop Year \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '1978' | System | 22 Aug 2020 18:23:16 |

US3532063

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:35:30

Condition

| Audit                                                                                                                                                                                 | User                   | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------|----------------------|
| User coded data point as SOC: General disorders and administration site conditions, HLGT: Tissue disorders NEC, HLT: Mass conditions NEC, PT: Cyst, LLT: Cyst - version MedDRA\\23.0. | Coder Import (b) (4)   | 27 Aug 2020 18:57:26 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.                                                                                               | Coder Import (b) (4)   | 27 Aug 2020 18:57:26 |
| Data point term sent to Coder                                                                                                                                                         | System                 | 22 Aug 2020 18:25:53 |
| User entered 'CYST ON NECK benign' reason for change: Data Entry Error                                                                                                                | Kathy Stephens (b) (4) | 22 Aug 2020 18:25:51 |
| Data point term sent to Coder                                                                                                                                                         | System                 | 22 Aug 2020 18:24:53 |
| User entered 'Cyst on nect'                                                                                                                                                           | Kathy Stephens (b) (4) | 22 Aug 2020 18:24:43 |

US3532063

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 09:35:30**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                              | Time (GMT)           |
|----------------------------|-----------------------------------|----------------------|
| User entered 'un UNK 2017' | Kathy Stephens (b) (4)<br>(b) (4) | 22 Aug 2020 18:24:43 |

US3532063

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 09:35:30**

[Start date completely unknown](#)

| Audit            | User                              | Time (GMT)           |
|------------------|-----------------------------------|----------------------|
| User entered '0' | Kathy Stephens (b) (4)<br>(b) (4) | 22 Aug 2020 18:24:43 |

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**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 09:35:30**

[Condition ongoing at study entry](#)

| Audit                 | User                              | Time (GMT)           |
|-----------------------|-----------------------------------|----------------------|
| User entered 'No (N)' | Kathy Stephens (b) (4)<br>(b) (4) | 22 Aug 2020 18:24:43 |

US3532063

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 09:35:30**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

| Audit                      | User                              | Time (GMT)           |
|----------------------------|-----------------------------------|----------------------|
| User entered 'un UNK 2017' | Kathy Stephens (b) (4)<br>(b) (4) | 22 Aug 2020 18:24:43 |

US3532063

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 09:35:30**

[Stop date completely unknown](#)

| Audit            | User                              | Time (GMT)           |
|------------------|-----------------------------------|----------------------|
| User entered '0' | Kathy Stephens (b) (4)<br>(b) (4) | 22 Aug 2020 18:24:43 |

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**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 09:35:30**

[Start Month and Year \(derived\)](#)

| Audit                   | User   | Time (GMT)           |
|-------------------------|--------|----------------------|
| User entered 'Jan 2017' | System | 22 Aug 2020 18:24:43 |



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**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 09:35:30**

[Start Year \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '2017' | System | 22 Aug 2020 18:24:43 |

US3532063

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 09:35:30**

[Stop Month and Year \(derived\)](#)

| Audit                   | User   | Time (GMT)           |
|-------------------------|--------|----------------------|
| User entered 'Jan 2017' | System | 22 Aug 2020 18:24:43 |

US3532063

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 09:35:30**

[Stop Year \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '2017' | System | 22 Aug 2020 18:24:43 |

US3532063

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:35:30

[Condition](#)

| Audit                                                                                                                                                                                                                                                                    | User                              | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------|----------------------|
| User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Breast neoplasms benign (incl nipple), HLT: Breast and nipple neoplasms benign, PT: Benign breast neoplasm, LLT: Benign breast neoplasm - version MedDRA\\23.0. | Coder Import (b) (4)<br>(b) (4)   | 27 Aug 2020 18:08:44 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.                                                                                                                                                                                  | Coder Import (b) (4)<br>(b) (4)   | 27 Aug 2020 18:08:44 |
| Data point term sent to Coder                                                                                                                                                                                                                                            | System                            | 22 Aug 2020 18:25:53 |
| User entered 'Breast node - Benign'                                                                                                                                                                                                                                      | Kathy Stephens (b) (4)<br>(b) (4) | 22 Aug 2020 18:25:23 |

US3532063

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 26 Nov 2020 09:35:30**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                              | Time (GMT)           |
|----------------------------|-----------------------------------|----------------------|
| User entered 'un UNK 2010' | Kathy Stephens (b) (4)<br>(b) (4) | 22 Aug 2020 18:25:23 |

US3532063

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 26 Nov 2020 09:35:30**

[Start date completely unknown](#)

| Audit            | User                              | Time (GMT)           |
|------------------|-----------------------------------|----------------------|
| User entered '0' | Kathy Stephens (b) (4)<br>(b) (4) | 22 Aug 2020 18:25:23 |

US3532063

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 26 Nov 2020 09:35:30**

[Condition ongoing at study entry](#)

| Audit                 | User                              | Time (GMT)           |
|-----------------------|-----------------------------------|----------------------|
| User entered 'No (N)' | Kathy Stephens (b) (4)<br>(b) (4) | 22 Aug 2020 18:25:23 |

US3532063

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 26 Nov 2020 09:35:30**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

| Audit                      | User                              | Time (GMT)           |
|----------------------------|-----------------------------------|----------------------|
| User entered 'un UNK 2010' | Kathy Stephens (b) (4)<br>(b) (4) | 22 Aug 2020 18:25:23 |



US3532063

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 26 Nov 2020 09:35:30**

[Stop date completely unknown](#)

| Audit            | User                              | Time (GMT)           |
|------------------|-----------------------------------|----------------------|
| User entered '0' | Kathy Stephens (b) (4)<br>(b) (4) | 22 Aug 2020 18:25:23 |

US3532063

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 26 Nov 2020 09:35:30**

[Start Month and Year \(derived\)](#)

| Audit                   | User   | Time (GMT)           |
|-------------------------|--------|----------------------|
| User entered 'Jan 2010' | System | 22 Aug 2020 18:25:23 |

US3532063

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 26 Nov 2020 09:35:30**

[Start Year \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '2010' | System | 22 Aug 2020 18:25:23 |

US3532063

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 26 Nov 2020 09:35:30**

[Stop Month and Year \(derived\)](#)

| Audit                   | User   | Time (GMT)           |
|-------------------------|--------|----------------------|
| User entered 'Jan 2010' | System | 22 Aug 2020 18:25:23 |

US3532063

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 26 Nov 2020 09:35:30**

[Stop Year \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '2010' | System | 22 Aug 2020 18:25:23 |

US3532063

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:35:30

[Condition](#)

| Audit                                                                                                                                                                        | User                   | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------|----------------------|
| User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0. | Coder Import (b) (4)   | 22 Aug 2020 18:28:12 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.                                                                                 | Coder Import (b) (4)   | 22 Aug 2020 18:28:12 |
| Data point term sent to Coder                                                                                                                                                | System                 | 22 Aug 2020 18:26:54 |
| User entered 'Seasonal Allergies'                                                                                                                                            | Kathy Stephens (b) (4) | 22 Aug 2020 18:26:19 |

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**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 26 Nov 2020 09:35:30**

[Start date \(dd MMM yyyy\)](#)

| Audit               | User                              | Time (GMT)           |
|---------------------|-----------------------------------|----------------------|
| User entered empty. | Kathy Stephens (b) (4)<br>(b) (4) | 22 Aug 2020 18:26:19 |

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**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 26 Nov 2020 09:35:30**

[Start date completely unknown](#)

| Audit            | User                              | Time (GMT)           |
|------------------|-----------------------------------|----------------------|
| User entered '1' | Kathy Stephens (b) (4)<br>(b) (4) | 22 Aug 2020 18:26:19 |



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Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:35:30

[Condition ongoing at study entry](#)

| Audit                                                                                                                                                        | User                              | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------|----------------------|
| User closed query 'Ongoing is reported as No, but Stop Date is missing and Stop Date completely unknown is not checked. Please provide.' (Site from System). | System                            | 22 Aug 2020 18:27:13 |
| User entered 'Yes (Y)' reason for change: Data Entry Error                                                                                                   | Kathy Stephens (b) (4)<br>(b) (4) | 22 Aug 2020 18:27:13 |
| User opened query 'Ongoing is reported as No, but Stop Date is missing and Stop Date completely unknown is not checked. Please provide.' (Site from System). | System                            | 22 Aug 2020 18:26:19 |
| User entered 'No (N)'                                                                                                                                        | Kathy Stephens (b) (4)<br>(b) (4) | 22 Aug 2020 18:26:19 |

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**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 26 Nov 2020 09:35:30**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

| Audit               | User                              | Time (GMT)           |
|---------------------|-----------------------------------|----------------------|
| User entered empty. | Kathy Stephens (b) (4)<br>(b) (4) | 22 Aug 2020 18:26:19 |

US3532063

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 26 Nov 2020 09:35:30**

[Stop date completely unknown](#)

| Audit            | User                              | Time (GMT)           |
|------------------|-----------------------------------|----------------------|
| User entered '0' | Kathy Stephens (b) (4)<br>(b) (4) | 22 Aug 2020 18:26:19 |

US3532063

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 26 Nov 2020 09:35:30**

[Start Month and Year \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 22 Aug 2020 18:26:19 |

US3532063

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 26 Nov 2020 09:35:30**

[Start Year \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 22 Aug 2020 18:26:19 |

US3532063

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 26 Nov 2020 09:35:30**

[Stop Month and Year \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 22 Aug 2020 18:26:19 |

US3532063

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 26 Nov 2020 09:35:30**

[Stop Year \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 22 Aug 2020 18:26:19 |

US3532063

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:35:30

[Condition](#)

| Audit                                                                                                                                                                                                                    | User                   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------|----------------------|
| User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Rubber sensitivity, LLT: Latex allergy - version MedDRA\\23.0. | Coder Import (b) (4)   | 22 Aug 2020 18:28:13 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.                                                                                                                             | Coder Import (b) (4)   | 22 Aug 2020 18:28:13 |
| Data point term sent to Coder                                                                                                                                                                                            | System                 | 22 Aug 2020 18:27:54 |
| User entered 'Latex allergy'                                                                                                                                                                                             | Kathy Stephens (b) (4) | 22 Aug 2020 18:26:57 |



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**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 26 Nov 2020 09:35:30**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                              | Time (GMT)           |
|----------------------------|-----------------------------------|----------------------|
| User entered 'un UNK 2000' | Kathy Stephens (b) (4)<br>(b) (4) | 22 Aug 2020 18:26:57 |

US3532063

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 26 Nov 2020 09:35:30**

[Start date completely unknown](#)

| Audit            | User                              | Time (GMT)           |
|------------------|-----------------------------------|----------------------|
| User entered '0' | Kathy Stephens (b) (4)<br>(b) (4) | 22 Aug 2020 18:26:57 |

US3532063

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 26 Nov 2020 09:35:30**

[Condition ongoing at study entry](#)

| Audit                  | User                              | Time (GMT)           |
|------------------------|-----------------------------------|----------------------|
| User entered 'Yes (Y)' | Kathy Stephens (b) (4)<br>(b) (4) | 22 Aug 2020 18:26:57 |

US3532063

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 26 Nov 2020 09:35:30**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

| Audit               | User                              | Time (GMT)           |
|---------------------|-----------------------------------|----------------------|
| User entered empty. | Kathy Stephens (b) (4)<br>(b) (4) | 22 Aug 2020 18:26:57 |

US3532063

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 26 Nov 2020 09:35:30**

[Stop date completely unknown](#)

| Audit            | User                              | Time (GMT)           |
|------------------|-----------------------------------|----------------------|
| User entered '0' | Kathy Stephens (b) (4)<br>(b) (4) | 22 Aug 2020 18:26:57 |

US3532063

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 26 Nov 2020 09:35:30**

[Start Month and Year \(derived\)](#)

| Audit                   | User   | Time (GMT)           |
|-------------------------|--------|----------------------|
| User entered 'Jan 2000' | System | 22 Aug 2020 18:26:57 |

US3532063

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 26 Nov 2020 09:35:30**

[Start Year \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '2000' | System | 22 Aug 2020 18:26:57 |

US3532063

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 26 Nov 2020 09:35:30**

[Stop Month and Year \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 22 Aug 2020 18:26:57 |



US3532063

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 26 Nov 2020 09:35:30**

[Stop Year \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 22 Aug 2020 18:26:57 |

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Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:35:30

[Condition](#)

| Audit                                                                                                                                                         | User                   | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------|----------------------|
| User coded data point as SOC: Social circumstances, HLGT: Age related factors, HLT: Age related issues, PT: Menopause, LLT: Menopause - version MedDRA\\23.0. | Coder Import (b) (4)   | 04 Sep 2020 18:07:39 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.                                                                  | (b) (4)                | 04 Sep 2020 18:07:39 |
| Data point term sent to Coder                                                                                                                                 | System                 | 04 Sep 2020 18:07:19 |
| User entered 'Menopause'                                                                                                                                      | Kathy Stephens (b) (4) | 04 Sep 2020 18:06:47 |
|                                                                                                                                                               | (b) (4)                |                      |

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**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 26 Nov 2020 09:35:30**

[Start date \(dd MMM yyyy\)](#)

| Audit                                                             | User                              | Time (GMT)           |
|-------------------------------------------------------------------|-----------------------------------|----------------------|
| User entered 'UN UNK 2000' reason for change:<br>Data Entry Error | Kathy Stephens (b) (4)<br>(b) (4) | 04 Sep 2020 18:07:18 |
| User entered 'un UNK 2004'                                        | Kathy Stephens (b) (4)<br>(b) (4) | 04 Sep 2020 18:06:47 |

US3532063

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 26 Nov 2020 09:35:30**

[Start date completely unknown](#)

| Audit            | User                              | Time (GMT)           |
|------------------|-----------------------------------|----------------------|
| User entered '0' | Kathy Stephens (b) (4)<br>(b) (4) | 04 Sep 2020 18:06:47 |

US3532063

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 26 Nov 2020 09:35:30**

[Condition ongoing at study entry](#)

| Audit                  | User                              | Time (GMT)           |
|------------------------|-----------------------------------|----------------------|
| User entered 'Yes (Y)' | Kathy Stephens (b) (4)<br>(b) (4) | 04 Sep 2020 18:06:47 |

US3532063

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 26 Nov 2020 09:35:30**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

| Audit               | User                              | Time (GMT)           |
|---------------------|-----------------------------------|----------------------|
| User entered empty. | Kathy Stephens (b) (4)<br>(b) (4) | 04 Sep 2020 18:06:47 |

US3532063

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 26 Nov 2020 09:35:30**

[Stop date completely unknown](#)

| Audit            | User                              | Time (GMT)           |
|------------------|-----------------------------------|----------------------|
| User entered '0' | Kathy Stephens (b) (4)<br>(b) (4) | 04 Sep 2020 18:06:47 |

US3532063

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 26 Nov 2020 09:35:30**

[Start Month and Year \(derived\)](#)

| Audit                   | User   | Time (GMT)           |
|-------------------------|--------|----------------------|
| User entered 'Jan 2000' | System | 04 Sep 2020 18:07:18 |
| User entered 'Jan 2004' | System | 04 Sep 2020 18:06:47 |



US3532063

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 26 Nov 2020 09:35:30**

[Start Year \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '2000' | System | 04 Sep 2020 18:07:18 |
| User entered '2004' | System | 04 Sep 2020 18:06:47 |

US3532063

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 26 Nov 2020 09:35:30**

[Stop Month and Year \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 04 Sep 2020 18:06:47 |

US3532063

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 26 Nov 2020 09:35:30**

[Stop Year \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 04 Sep 2020 18:06:47 |

US3532063

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:35:30

[Were vital signs assessed?](#)

| Audit                                                                                                                                  | User                   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------|------------------------|----------------------|
| User closed query 'Response to were vital signs assessed is No, but data is provided below. Please correct.' (Site from System).       | System                 | 22 Aug 2020 18:30:28 |
| User closed query 'Response to were vital signs assessed is No, but height or weight is provided. Please correct.' (Site from System). | System                 | 22 Aug 2020 18:30:28 |
| User entered 'Yes (Y)' reason for change: Data Entry Error                                                                             | Kathy Stephens (b) (4) | 22 Aug 2020 18:30:28 |
| User opened query 'Response to were vital signs assessed is No, but data is provided below. Please correct.' (Site from System).       | System                 | 22 Aug 2020 18:30:20 |
| User opened query 'Response to were vital signs assessed is No, but height or weight is provided. Please correct.' (Site from System). | System                 | 18 Aug 2020 18:36:28 |
| User entered 'No (N)'                                                                                                                  | Kathy Stephens (b) (4) | 18 Aug 2020 18:36:28 |

US3532063

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:35:30

Date of assessment (*dd MMM yyyy*)

| Audit                                                                     | User                   | Time (GMT)           |
|---------------------------------------------------------------------------|------------------------|----------------------|
| User closed query 'Data is required. Please provide.' (Site from System). | System                 | 22 Aug 2020 18:30:39 |
| User entered '18 Aug 2020' reason for change: Data Entry Error            | Kathy Stephens (b) (4) | 22 Aug 2020 18:30:39 |
| User opened query 'Data is required. Please provide.' (Site from System). | System                 | 22 Aug 2020 18:30:28 |
| User entered empty.                                                       | Kathy Stephens (b) (4) | 18 Aug 2020 18:36:28 |

US3532063

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 09:35:30**

[Time of assessment \(00:00-23:59\)](#)

| Audit                                                    | User                   | Time (GMT)           |
|----------------------------------------------------------|------------------------|----------------------|
| User entered '13:49' reason for change: Data Entry Error | Kathy Stephens (b) (4) | 22 Aug 2020 18:30:20 |
| User entered empty.                                      | Kathy Stephens (b) (4) | 18 Aug 2020 18:36:28 |

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**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 09:35:30**

[Vital Signs Date and Time \(derived\)](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '18 Aug 2020 13:49' | System | 22 Aug 2020 18:30:39 |
| User entered empty.              | System | 18 Aug 2020 18:36:28 |

US3532063

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:35:30

[Height \(xxx.x\)](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| User entered '169.5' cm   | Kathy Stephens (b) (4) | 18 Aug 2020 18:36:28 |
| DataPoint set to visible. | (b) (4)<br>System      | 18 Aug 2020 18:35:01 |



US3532063

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:35:30

[Weight \(xxx.x\)](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| User entered '49.9' kg    | Kathy Stephens (b) (4) | 18 Aug 2020 18:36:28 |
| DataPoint set to visible. | (b) (4)<br>System      | 18 Aug 2020 18:35:01 |

US3532063

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:35:30

BMI (xxx.x)

| Audit                                      | User   | Time (GMT)           |
|--------------------------------------------|--------|----------------------|
| Amendment Manager: User entered '17.36845' | System | 17 Sep 2020 00:12:24 |
| User entered '17.4'                        | System | 18 Aug 2020 18:36:28 |
| DataPoint set to visible.                  | System | 18 Aug 2020 18:35:01 |

US3532063

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:35:30

[BMI units](#)

| Audit                     | User   | Time (GMT)           |
|---------------------------|--------|----------------------|
| User entered 'kg/m2'      | System | 18 Aug 2020 18:36:28 |
| DataPoint set to visible. | System | 18 Aug 2020 18:35:01 |

US3532063

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:35:30

Temperature (xxx.x)

| Audit                                                                       | User                   | Time (GMT)           |
|-----------------------------------------------------------------------------|------------------------|----------------------|
| User entered missing code ND - Not Done; reason for change Data Entry Error | Kathy Stephens (b) (4) | 22 Aug 2020 18:30:20 |
| User entered empty.                                                         | Kathy Stephens (b) (4) | 18 Aug 2020 18:36:28 |

US3532063

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 09:35:30**

[Route of measurement](#)

| Audit               | User                              | Time (GMT)           |
|---------------------|-----------------------------------|----------------------|
| User entered empty. | Kathy Stephens (b) (4)<br>(b) (4) | 18 Aug 2020 18:36:28 |

US3532063

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 09:35:30**

[If Other, specify](#)

| Audit               | User                              | Time (GMT)           |
|---------------------|-----------------------------------|----------------------|
| User entered empty. | Kathy Stephens (b) (4)<br>(b) (4) | 18 Aug 2020 18:36:28 |

US3532063

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:35:30

[Pulse \(xxx\)](#)

| Audit                                                                       | User                   | Time (GMT)           |
|-----------------------------------------------------------------------------|------------------------|----------------------|
| User entered missing code ND - Not Done; reason for change Data Entry Error | Kathy Stephens (b) (4) | 22 Aug 2020 18:30:20 |
| User entered empty.                                                         | Kathy Stephens (b) (4) | 18 Aug 2020 18:36:28 |

US3532063

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 09:35:30**

[Pulse units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'bpm'  | System | 22 Aug 2020 18:30:20 |
| User entered empty. | System | 18 Aug 2020 18:36:28 |



US3532063

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:35:30

[Respiratory Rate \(xxx\)](#)

| Audit                                                                       | User                   | Time (GMT)           |
|-----------------------------------------------------------------------------|------------------------|----------------------|
| User entered missing code ND - Not Done; reason for change Data Entry Error | Kathy Stephens (b) (4) | 22 Aug 2020 18:30:20 |
| User entered empty.                                                         | Kathy Stephens (b) (4) | 18 Aug 2020 18:36:28 |

US3532063

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 09:35:30**

[Respiratory Rate units](#)

| Audit                      | User   | Time (GMT)           |
|----------------------------|--------|----------------------|
| User entered 'breaths/min' | System | 22 Aug 2020 18:30:20 |
| User entered empty.        | System | 18 Aug 2020 18:36:28 |

US3532063

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:35:30

Systolic Blood Pressure (xxx)

| Audit                                                                       | User                   | Time (GMT)           |
|-----------------------------------------------------------------------------|------------------------|----------------------|
| User entered missing code ND - Not Done; reason for change Data Entry Error | Kathy Stephens (b) (4) | 22 Aug 2020 18:30:20 |
| User entered empty.                                                         | Kathy Stephens (b) (4) | 18 Aug 2020 18:36:28 |

US3532063

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 09:35:30**

[Systolic Blood Pressure units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 22 Aug 2020 18:30:20 |
| User entered empty. | System | 18 Aug 2020 18:36:28 |

US3532063

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 09:35:30**

[Diastolic Blood Pressure \(xxx\)](#)

| Audit                                                                       | User                   | Time (GMT)           |
|-----------------------------------------------------------------------------|------------------------|----------------------|
| User entered missing code ND - Not Done; reason for change Data Entry Error | Kathy Stephens (b) (4) | 22 Aug 2020 18:30:20 |
| User entered empty.                                                         | Kathy Stephens (b) (4) | 18 Aug 2020 18:36:28 |

US3532063

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 09:35:30**

[Diastolic Blood Pressure units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 22 Aug 2020 18:30:20 |
| User entered empty. | System | 18 Aug 2020 18:36:28 |

US3532063

**Folder: Screening**

**Form: Physical Examination**

**Generated On: 26 Nov 2020 09:35:30**

[Was the physical examination performed?](#)

| Audit                                                     | User                   | Time (GMT)           |
|-----------------------------------------------------------|------------------------|----------------------|
| User entered 'No (N)' reason for change: Data Entry Error | Kathy Stephens (b) (4) | 18 Sep 2020 13:24:18 |
| User entered 'Yes (Y)'                                    | Kathy Stephens (b) (4) | 18 Aug 2020 18:53:26 |

US3532063

**Folder: Screening**

**Form: Physical Examination**

**Generated On: 26 Nov 2020 09:35:30**

**Date of examination (dd MMM yyyy)**

| Audit                                                                                                                                    | User                   | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------------------------------------|------------------------|----------------------|
| User closed query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System). | System                 | 18 Sep 2020 13:24:18 |
| User entered empty; reason for change Data Entry Error                                                                                   | Kathy Stephens (b) (4) | 18 Sep 2020 13:24:18 |
| User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System). | System                 | 16 Sep 2020 18:40:16 |
| User entered '18 Aug 2020'                                                                                                               | Kathy Stephens (b) (4) | 18 Aug 2020 18:53:26 |



US3532063

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 26 Nov 2020 09:35:30**

[Date of assessment \(dd MMM yyyy\)](#)

| Audit                      | User                              | Time (GMT)           |
|----------------------------|-----------------------------------|----------------------|
| User entered '18 Aug 2020' | Kathy Stephens (b) (4)<br>(b) (4) | 18 Aug 2020 18:54:24 |

US3532063

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 26 Nov 2020 09:35:30**

[Is the participant of childbearing potential?](#)

| Audit                 | User                              | Time (GMT)           |
|-----------------------|-----------------------------------|----------------------|
| User entered 'No (N)' | Kathy Stephens (b) (4)<br>(b) (4) | 18 Aug 2020 18:54:24 |

US3532063

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:35:30

If No, what is the reason?

| Audit                                                                                                                                                                                                                                                                                             | User                   | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------|----------------------|
| User closed query 'Per CDM: "If No, what is the reason" is "Post-menopausal"; however the condition is not recorded in "Medical History" form. Please refer to page 22 of CCGs, and update all relevant medical conditions in "Medical History" form. Thank you.' (Site from DM).                 | (b) (4), (b) (6)       | 08 Sep 2020 08:37:25 |
| Query 'Per CDM: "If No, what is the reason" is "Post-menopausal"; however the condition is not recorded in "Medical History" form. Please refer to page 22 of CCGs, and update all relevant medical conditions in "Medical History" form. Thank you.' answered with 'added ti MH' (Site from DM). | Kathy Stephens (b) (4) | 04 Sep 2020 18:08:27 |
| User opened query 'Per CDM: "If No, what is the reason" is "Post-menopausal"; however the condition is not recorded in "Medical History" form. Please refer to page 22 of CCGs, and update all relevant medical conditions in "Medical History" form. Thank you.' (Site from DM).                 | (b) (4), (b) (6)       | 04 Sep 2020 06:51:44 |
| User entered 'Post-menopausal (POST-MENOPAUSAL)'                                                                                                                                                                                                                                                  | Kathy Stephens (b) (4) | 18 Aug 2020 18:54:24 |

US3532063

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 26 Nov 2020 09:35:30**

[If Partner medically sterile or Other, specify](#)

| Audit               | User                              | Time (GMT)           |
|---------------------|-----------------------------------|----------------------|
| User entered empty. | Kathy Stephens (b) (4)<br>(b) (4) | 18 Aug 2020 18:54:24 |

US3532063

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 26 Nov 2020 09:35:30**

If Surgically sterile, date of surgery (*dd MMM yyyy*)

| Audit               | User                              | Time (GMT)           |
|---------------------|-----------------------------------|----------------------|
| User entered empty. | Kathy Stephens (b) (4)<br>(b) (4) | 18 Aug 2020 18:54:24 |

US3532063

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 26 Nov 2020 09:35:30**

[Date of surgery unknown](#)

| Audit            | User                              | Time (GMT)           |
|------------------|-----------------------------------|----------------------|
| User entered '0' | Kathy Stephens (b) (4)<br>(b) (4) | 18 Aug 2020 18:54:24 |

US3532063

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 26 Nov 2020 09:35:30**

If Post-menopausal, date of last menstruation (*dd MMM yyyy*)

| Audit                      | User                              | Time (GMT)           |
|----------------------------|-----------------------------------|----------------------|
| User entered 'un UNK 2000' | Kathy Stephens (b) (4)<br>(b) (4) | 18 Aug 2020 18:54:24 |

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**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 26 Nov 2020 09:35:30**

[Date of last menstruation unknown](#)

| Audit            | User                              | Time (GMT)           |
|------------------|-----------------------------------|----------------------|
| User entered '0' | Kathy Stephens (b) (4)<br>(b) (4) | 18 Aug 2020 18:54:24 |



US3532063

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:35:30

[Healthcare workers](#) (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

| Audit                                                                                  | User                   | Time (GMT)           |
|----------------------------------------------------------------------------------------|------------------------|----------------------|
| User closed query 'Data is required. Please complete.' (Site from System).             | System                 | 18 Aug 2020 18:55:32 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System                 | 18 Aug 2020 18:55:32 |
| User entered 'No (N)' reason for change: Data Entry Error                              | Kathy Stephens (b) (4) | 18 Aug 2020 18:55:32 |
| User opened query 'Data is required. Please complete.' (Site from System).             | System                 | 18 Aug 2020 18:54:58 |
| User entered empty.                                                                    | Kathy Stephens (b) (4) | 18 Aug 2020 18:54:58 |

US3532063

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 26 Nov 2020 09:35:30**

**Emergency Response** (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

| Audit                                                                                  | User                              | Time (GMT)           |
|----------------------------------------------------------------------------------------|-----------------------------------|----------------------|
| User closed query 'Data is required. Please complete.' (Site from System).             | System                            | 18 Aug 2020 18:55:32 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System                            | 18 Aug 2020 18:55:32 |
| User entered 'No (N)' reason for change: Data Entry Error                              | Kathy Stephens (b) (4)<br>(b) (4) | 18 Aug 2020 18:55:32 |
| User opened query 'Data is required. Please complete.' (Site from System).             | System                            | 18 Aug 2020 18:54:58 |
| User entered empty.                                                                    | Kathy Stephens (b) (4)<br>(b) (4) | 18 Aug 2020 18:54:58 |

US3532063

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 26 Nov 2020 09:35:30**

**Retail or Restaurant Operations**, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

| Audit                                                                                  | User                              | Time (GMT)           |
|----------------------------------------------------------------------------------------|-----------------------------------|----------------------|
| User closed query 'Data is required. Please complete.' (Site from System).             | System                            | 18 Aug 2020 18:55:32 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System                            | 18 Aug 2020 18:55:32 |
| User entered 'No (N)' reason for change: Data Entry Error                              | Kathy Stephens (b) (4)<br>(b) (4) | 18 Aug 2020 18:55:32 |
| User opened query 'Data is required. Please complete.' (Site from System).             | System                            | 18 Aug 2020 18:54:58 |
| User entered empty.                                                                    | Kathy Stephens (b) (4)<br>(b) (4) | 18 Aug 2020 18:54:58 |

US3532063

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:35:30

**Manufacturing & Production Operations** with inherent overcrowding (e.g., factory workers, meat/food processing plants)

| Audit                                                                                  | User                              | Time (GMT)           |
|----------------------------------------------------------------------------------------|-----------------------------------|----------------------|
| User closed query 'Data is required. Please complete.' (Site from System).             | System                            | 18 Aug 2020 18:55:32 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System                            | 18 Aug 2020 18:55:32 |
| User entered 'No (N)' reason for change: Data Entry Error                              | Kathy Stephens (b) (4)<br>(b) (4) | 18 Aug 2020 18:55:32 |
| User opened query 'Data is required. Please complete.' (Site from System).             | System                            | 18 Aug 2020 18:54:58 |
| User entered empty.                                                                    | Kathy Stephens (b) (4)<br>(b) (4) | 18 Aug 2020 18:54:58 |

US3532063

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:35:30

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

| Audit                                                                                  | User                              | Time (GMT)           |
|----------------------------------------------------------------------------------------|-----------------------------------|----------------------|
| User closed query 'Data is required. Please complete.' (Site from System).             | System                            | 18 Aug 2020 18:55:32 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System                            | 18 Aug 2020 18:55:32 |
| User entered 'No (N)' reason for change: Data Entry Error                              | Kathy Stephens (b) (4)<br>(b) (4) | 18 Aug 2020 18:55:32 |
| User opened query 'Data is required. Please complete.' (Site from System).             | System                            | 18 Aug 2020 18:54:58 |
| User entered empty.                                                                    | Kathy Stephens (b) (4)<br>(b) (4) | 18 Aug 2020 18:54:58 |

US3532063

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 26 Nov 2020 09:35:30**

**Transportation and delivery services** (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

| Audit                                                                                  | User                   | Time (GMT)           |
|----------------------------------------------------------------------------------------|------------------------|----------------------|
| User closed query 'Data is required. Please complete.' (Site from System).             | System                 | 18 Aug 2020 18:55:32 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System                 | 18 Aug 2020 18:55:32 |
| User entered 'No (N)' reason for change: Data Entry Error                              | Kathy Stephens (b) (4) | 18 Aug 2020 18:55:32 |
| User opened query 'Data is required. Please complete.' (Site from System).             | System                 | 18 Aug 2020 18:54:58 |
| User entered empty.                                                                    | Kathy Stephens (b) (4) | 18 Aug 2020 18:54:58 |

US3532063

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 26 Nov 2020 09:35:30**

**Border Protection and Military Personnel** (e.g., TSA, custom and border protection agents, military personnel not social distancing)

| Audit                                                                                  | User                              | Time (GMT)           |
|----------------------------------------------------------------------------------------|-----------------------------------|----------------------|
| User closed query 'Data is required. Please complete.' (Site from System).             | System                            | 18 Aug 2020 18:55:32 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System                            | 18 Aug 2020 18:55:32 |
| User entered 'No (N)' reason for change: Data Entry Error                              | Kathy Stephens (b) (4)<br>(b) (4) | 18 Aug 2020 18:55:32 |
| User opened query 'Data is required. Please complete.' (Site from System).             | System                            | 18 Aug 2020 18:54:58 |
| User entered empty.                                                                    | Kathy Stephens (b) (4)<br>(b) (4) | 18 Aug 2020 18:54:58 |

US3532063

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 26 Nov 2020 09:35:30**

**Personal Care and in-home services** (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

| Audit                                                                                  | User                   | Time (GMT)           |
|----------------------------------------------------------------------------------------|------------------------|----------------------|
| User closed query 'Data is required. Please complete.' (Site from System).             | System                 | 18 Aug 2020 18:55:32 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System                 | 18 Aug 2020 18:55:32 |
| User entered 'No (N)' reason for change: Data Entry Error                              | Kathy Stephens (b) (4) | 18 Aug 2020 18:55:32 |
| User opened query 'Data is required. Please complete.' (Site from System).             | System                 | 18 Aug 2020 18:54:58 |
| User entered empty.                                                                    | Kathy Stephens (b) (4) | 18 Aug 2020 18:54:58 |



US3532063

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:35:30

[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

| Audit                                                                                  | User                              | Time (GMT)           |
|----------------------------------------------------------------------------------------|-----------------------------------|----------------------|
| User closed query 'Data is required. Please complete.' (Site from System).             | System                            | 18 Aug 2020 18:55:32 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System                            | 18 Aug 2020 18:55:32 |
| User entered 'No (N)' reason for change: Data Entry Error                              | Kathy Stephens (b) (4)<br>(b) (4) | 18 Aug 2020 18:55:32 |
| User opened query 'Data is required. Please complete.' (Site from System).             | System                            | 18 Aug 2020 18:54:58 |
| User entered empty.                                                                    | Kathy Stephens (b) (4)<br>(b) (4) | 18 Aug 2020 18:54:58 |

US3532063

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 26 Nov 2020 09:35:30**

**Pastoral, Social or Public Health Workers** requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

| Audit                                                                                  | User                              | Time (GMT)           |
|----------------------------------------------------------------------------------------|-----------------------------------|----------------------|
| User closed query 'Data is required. Please complete.' (Site from System).             | System                            | 18 Aug 2020 18:55:32 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System                            | 18 Aug 2020 18:55:32 |
| User entered 'No (N)' reason for change: Data Entry Error                              | Kathy Stephens (b) (4)<br>(b) (4) | 18 Aug 2020 18:55:32 |
| User opened query 'Data is required. Please complete.' (Site from System).             | System                            | 18 Aug 2020 18:54:58 |
| User entered empty.                                                                    | Kathy Stephens (b) (4)<br>(b) (4) | 18 Aug 2020 18:54:58 |

US3532063

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 26 Nov 2020 09:35:30**

**Educators and Students** (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

| Audit                                                                                  | User                              | Time (GMT)           |
|----------------------------------------------------------------------------------------|-----------------------------------|----------------------|
| User closed query 'Data is required. Please complete.' (Site from System).             | System                            | 18 Aug 2020 18:55:32 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System                            | 18 Aug 2020 18:55:32 |
| User entered 'No (N)' reason for change: Data Entry Error                              | Kathy Stephens (b) (4)<br>(b) (4) | 18 Aug 2020 18:55:32 |
| User opened query 'Data is required. Please complete.' (Site from System).             | System                            | 18 Aug 2020 18:54:58 |
| User entered empty.                                                                    | Kathy Stephens (b) (4)<br>(b) (4) | 18 Aug 2020 18:54:58 |

US3532063

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:35:30

[Other](#)

| Audit                 | User                              | Time (GMT)           |
|-----------------------|-----------------------------------|----------------------|
| User entered 'No (N)' | Kathy Stephens (b) (4)<br>(b) (4) | 18 Aug 2020 18:54:58 |

US3532063

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:35:30

[Specify](#)

| Audit               | User                              | Time (GMT)           |
|---------------------|-----------------------------------|----------------------|
| User entered empty. | Kathy Stephens (b) (4)<br>(b) (4) | 18 Aug 2020 18:54:58 |

US3532063

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:35:30

No Risk Identified

| Audit            | User                              | Time (GMT)           |
|------------------|-----------------------------------|----------------------|
| User entered '0' | Kathy Stephens (b) (4)<br>(b) (4) | 18 Aug 2020 18:54:58 |

US3532063

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:35:30

[Resides in Nursing Home or Assisted Living Facility](#)

| Audit            | User                              | Time (GMT)           |
|------------------|-----------------------------------|----------------------|
| User entered '0' | Kathy Stephens (b) (4)<br>(b) (4) | 18 Aug 2020 18:54:58 |

US3532063

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:35:30

**Resides in Multi-family dwelling** (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

| Audit            | User                              | Time (GMT)           |
|------------------|-----------------------------------|----------------------|
| User entered '0' | Kathy Stephens (b) (4)<br>(b) (4) | 18 Aug 2020 18:54:58 |



US3532063

**Folder:** Screening

**Form:** Risk of Exposure

**Generated On:** 26 Nov 2020 09:35:30

**Resides in high density housing** (e.g., high rise apartments with shared entrances or elevators)

| Audit            | User                              | Time (GMT)           |
|------------------|-----------------------------------|----------------------|
| User entered '0' | Kathy Stephens (b) (4)<br>(b) (4) | 18 Aug 2020 18:54:58 |

US3532063

**Folder:** Screening

**Form:** Risk of Exposure

**Generated On:** 26 Nov 2020 09:35:30

**Resides in low density, multi-family setting without** (e.g., apartments complex without shared entrances or elevators, duplexes)

| Audit            | User                              | Time (GMT)           |
|------------------|-----------------------------------|----------------------|
| User entered '1' | Kathy Stephens (b) (4)<br>(b) (4) | 18 Aug 2020 18:54:58 |

US3532063

**Folder:** Screening

**Form:** Risk of Exposure

**Generated On:** 26 Nov 2020 09:35:30

**Resides in a single family home** (i.e., detached housing)

| Audit            | User                              | Time (GMT)           |
|------------------|-----------------------------------|----------------------|
| User entered '0' | Kathy Stephens (b) (4)<br>(b) (4) | 18 Aug 2020 18:54:58 |

US3532063

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:35:30

[Other](#)

| Audit            | User                              | Time (GMT)           |
|------------------|-----------------------------------|----------------------|
| User entered '0' | Kathy Stephens (b) (4)<br>(b) (4) | 18 Aug 2020 18:54:58 |

US3532063

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:35:30

[Specify](#)

| Audit               | User                              | Time (GMT)           |
|---------------------|-----------------------------------|----------------------|
| User entered empty. | Kathy Stephens (b) (4)<br>(b) (4) | 18 Aug 2020 18:54:58 |

US3532063

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:35:30

[Was this visit performed?](#)

| Audit                  | User                              | Time (GMT)           |
|------------------------|-----------------------------------|----------------------|
| User entered 'Yes (Y)' | Kathy Stephens (b) (4)<br>(b) (4) | 18 Aug 2020 17:52:41 |

US3532063

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 26 Nov 2020 09:35:30**

[Visit date \(dd MMM yyyy\)](#)

| Audit                      | User                              | Time (GMT)           |
|----------------------------|-----------------------------------|----------------------|
| User entered '18 Aug 2020' | Kathy Stephens (b) (4)<br>(b) (4) | 18 Aug 2020 17:52:41 |

US3532063

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:35:30

Was visit performed at the participant's home or at the clinic?

| Audit                          | User                              | Time (GMT)           |
|--------------------------------|-----------------------------------|----------------------|
| User entered 'Clinic (Clinic)' | Kathy Stephens (b) (4)<br>(b) (4) | 18 Aug 2020 17:52:41 |



US3532063

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 26 Nov 2020 09:35:30**

[Folder OID](#)

| Audit                 | User   | Time (GMT)           |
|-----------------------|--------|----------------------|
| User entered 'VISIT1' | System | 18 Aug 2020 17:52:41 |

US3532063

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:35:30

What was the date of randomization? (*dd MMM yyyy*)

| Audit                      | User                                            | Time (GMT)           |
|----------------------------|-------------------------------------------------|----------------------|
| User entered '18 AUG 2020' | RWS_ENDPOINT<br>ENDPOINT (b) (4)<br><div></div> | 18 Aug 2020 18:14:41 |

US3532063

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:35:30

What was the participant's randomization number?

| Audit                                                                                                      | User                                           | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------|------------------------------------------------|----------------------|
| Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System). | System                                         | 21 Aug 2020 05:21:19 |
| Amendment Manager: Data point set to conformant.                                                           | System                                         | 21 Aug 2020 05:21:19 |
| User opened query 'Data entered is non-conformant. Please correct.' (Site from System).                    | System                                         | 18 Aug 2020 18:14:41 |
| User entered '186760' (non-conformant).                                                                    | RWS_ENDPOINT<br>ENDPOINT (b) (4)<br>[REDACTED] | 18 Aug 2020 18:14:41 |

US3532063

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:35:30

[In what Cohort was the participant enrolled?](#)

| Audit                         | User                                            | Time (GMT)           |
|-------------------------------|-------------------------------------------------|----------------------|
| User entered '>=65 years (3)' | RWS_ENDPOINT<br>ENDPOINT (b) (4)<br><div></div> | 18 Aug 2020 18:14:41 |

US3532063

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 26 Nov 2020 09:35:30**

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

| Audit                 | User                              | Time (GMT)           |
|-----------------------|-----------------------------------|----------------------|
| User entered 'No (N)' | Kathy Stephens (b) (4)<br>(b) (4) | 18 Aug 2020 18:55:52 |

US3532063

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 26 Nov 2020 09:35:30**

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

| Audit                 | User                              | Time (GMT)           |
|-----------------------|-----------------------------------|----------------------|
| User entered 'No (N)' | Kathy Stephens (b) (4)<br>(b) (4) | 18 Aug 2020 18:55:52 |

US3532063

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 26 Nov 2020 09:35:30**

Severe obesity (body mass index > or = 40kg/m2)

| Audit                 | User                              | Time (GMT)           |
|-----------------------|-----------------------------------|----------------------|
| User entered 'No (N)' | Kathy Stephens (b) (4)<br>(b) (4) | 18 Aug 2020 18:55:52 |

US3532063

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 26 Nov 2020 09:35:30**

[Diabetes \(Type I, Type 2, or gestational\)](#)

| Audit                 | User                              | Time (GMT)           |
|-----------------------|-----------------------------------|----------------------|
| User entered 'No (N)' | Kathy Stephens (b) (4)<br>(b) (4) | 18 Aug 2020 18:55:52 |



US3532063

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:35:30

[Liver Disease](#)

| Audit                 | User                              | Time (GMT)           |
|-----------------------|-----------------------------------|----------------------|
| User entered 'No (N)' | Kathy Stephens (b) (4)<br>(b) (4) | 18 Aug 2020 18:55:52 |

US3532063

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 26 Nov 2020 09:35:30**

[Human Immunodeficiency Virus \(HIV\) infection](#)

| Audit                                        | User                | Time (GMT)           |
|----------------------------------------------|---------------------|----------------------|
| User entered 'No (N)'                        | Etza Peters (b) (4) | 25 Sep 2020 15:08:27 |
| Amendment Manager: DataPoint set to visible. | (b) (4)             | 19 Sep 2020 10:34:57 |
| Amendment Manager inserted this DataPoint.   | System              | 19 Sep 2020 01:20:19 |

US3532063

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:35:30

Height

| Audit                                                                       | User                   | Time (GMT)           |
|-----------------------------------------------------------------------------|------------------------|----------------------|
| User entered missing code ND - Not Done; reason for change Data Entry Error | Kathy Stephens (b) (4) | 22 Aug 2020 18:32:27 |
| User entered empty.                                                         | Kathy Stephens (b) (4) | 18 Aug 2020 18:57:33 |

US3532063

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:35:30

Weight

| Audit                                                                       | User                   | Time (GMT)           |
|-----------------------------------------------------------------------------|------------------------|----------------------|
| User entered missing code ND - Not Done; reason for change Data Entry Error | Kathy Stephens (b) (4) | 22 Aug 2020 18:32:27 |
| User entered empty.                                                         | Kathy Stephens (b) (4) | 18 Aug 2020 18:57:33 |

US3532063

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:35:30

Height

| Audit                                                                       | User                   | Time (GMT)           |
|-----------------------------------------------------------------------------|------------------------|----------------------|
| User entered missing code ND - Not Done; reason for change Data Entry Error | Kathy Stephens (b) (4) | 22 Aug 2020 18:32:27 |
| User entered empty.                                                         | Kathy Stephens (b) (4) | 18 Aug 2020 18:57:33 |

US3532063

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:35:30

Weight

| Audit                                                                       | User                   | Time (GMT)           |
|-----------------------------------------------------------------------------|------------------------|----------------------|
| User entered missing code ND - Not Done; reason for change Data Entry Error | Kathy Stephens (b) (4) | 22 Aug 2020 18:32:27 |
| User entered empty.                                                         | Kathy Stephens (b) (4) | 18 Aug 2020 18:57:33 |

US3532063

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:35:30

[Timepoint](#)

| Audit                                            | User                              | Time (GMT)           |
|--------------------------------------------------|-----------------------------------|----------------------|
| User accepted default value 'Pre-Dose (PREDOSE)' | Kathy Stephens (b) (4)<br>(b) (4) | 18 Aug 2020 18:57:33 |

US3532063

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:35:30

[Were vital signs assessed?](#)

| Audit                  | User                              | Time (GMT)           |
|------------------------|-----------------------------------|----------------------|
| User entered 'Yes (Y)' | Kathy Stephens (b) (4)<br>(b) (4) | 18 Aug 2020 18:57:33 |



US3532063

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:35:30

Date of assessment (*dd MMM yyyy*)

| Audit                      | User                              | Time (GMT)           |
|----------------------------|-----------------------------------|----------------------|
| User entered '18 Aug 2020' | Kathy Stephens (b) (4)<br>(b) (4) | 18 Aug 2020 18:57:33 |

US3532063

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 09:35:30**

[Time of assessment \(00:00-23:59\)](#)

| Audit                | User                              | Time (GMT)           |
|----------------------|-----------------------------------|----------------------|
| User entered '13:45' | Kathy Stephens (b) (4)<br>(b) (4) | 18 Aug 2020 18:57:33 |

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**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 09:35:30**

[Vital Signs Date and Time \(derived\)](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '18 Aug 2020 13:45' | System | 18 Aug 2020 18:57:33 |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:35:30

Temperature (xxx.x)

| Audit                 | User                              | Time (GMT)           |
|-----------------------|-----------------------------------|----------------------|
| User entered '97.1' F | Kathy Stephens (b) (4)<br>(b) (4) | 18 Aug 2020 18:57:33 |

US3532063

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:35:30

[Route of measurement](#)

| Audit                      | User                              | Time (GMT)           |
|----------------------------|-----------------------------------|----------------------|
| User entered 'Oral (Oral)' | Kathy Stephens (b) (4)<br>(b) (4) | 18 Aug 2020 18:57:33 |

US3532063

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:35:30

[If Other, specify](#)

| Audit               | User                              | Time (GMT)           |
|---------------------|-----------------------------------|----------------------|
| User entered empty. | Kathy Stephens (b) (4)<br>(b) (4) | 18 Aug 2020 18:57:33 |

US3532063

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:35:30

[Pulse \(xxx\)](#)

| Audit             | User                              | Time (GMT)           |
|-------------------|-----------------------------------|----------------------|
| User entered '76' | Kathy Stephens (b) (4)<br>(b) (4) | 18 Aug 2020 18:57:33 |

US3532063

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 09:35:30**

[Pulse units](#)

| Audit              | User   | Time (GMT)           |
|--------------------|--------|----------------------|
| User entered 'bpm' | System | 18 Aug 2020 18:57:33 |



US3532063

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:35:30

[Respiratory Rate \(xxx\)](#)

| Audit                                                                                   | User                              | Time (GMT)           |
|-----------------------------------------------------------------------------------------|-----------------------------------|----------------------|
| User closed query 'Data entered is non-conformant. Please correct.' (Site from System). | System                            | 22 Aug 2020 21:03:24 |
| User entered '18' reason for change: Data Entry Error                                   | Kathy Stephens (b) (4)<br>(b) (4) | 22 Aug 2020 21:03:24 |
| User opened query 'Data entered is non-conformant. Please correct.' (Site from System). | System                            | 18 Aug 2020 18:57:33 |
| User entered '18' (non-conformant).                                                     | Kathy Stephens (b) (4)<br>(b) (4) | 18 Aug 2020 18:57:33 |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:35:30

[Respiratory Rate units](#)

| Audit                      | User   | Time (GMT)           |
|----------------------------|--------|----------------------|
| User entered 'breaths/min' | System | 22 Aug 2020 21:03:24 |
| User entered empty.        | System | 18 Aug 2020 18:57:33 |

US3532063

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:35:30

Systolic Blood Pressure (xxx)

| Audit              | User                              | Time (GMT)           |
|--------------------|-----------------------------------|----------------------|
| User entered '103' | Kathy Stephens (b) (4)<br>(b) (4) | 18 Aug 2020 18:57:33 |

US3532063

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 09:35:30**

[Systolic Blood Pressure units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 18 Aug 2020 18:57:33 |

US3532063

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 09:35:30**

[Diastolic Blood Pressure \(xxx\)](#)

| Audit             | User                              | Time (GMT)           |
|-------------------|-----------------------------------|----------------------|
| User entered '64' | Kathy Stephens (b) (4)<br>(b) (4) | 18 Aug 2020 18:57:33 |

US3532063

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 09:35:30**

[Diastolic Blood Pressure units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 18 Aug 2020 18:57:33 |

US3532063

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:35:30

[Height](#)

| Audit                                                                       | User                   | Time (GMT)           |
|-----------------------------------------------------------------------------|------------------------|----------------------|
| User entered missing code ND - Not Done; reason for change Data Entry Error | Kathy Stephens (b) (4) | 22 Aug 2020 18:32:27 |
| User entered empty.                                                         | Kathy Stephens (b) (4) | 18 Aug 2020 18:57:33 |

US3532063

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:35:30

Weight

| Audit                                                                       | User                   | Time (GMT)           |
|-----------------------------------------------------------------------------|------------------------|----------------------|
| User entered missing code ND - Not Done; reason for change Data Entry Error | Kathy Stephens (b) (4) | 22 Aug 2020 18:32:27 |
| User entered empty.                                                         | Kathy Stephens (b) (4) | 18 Aug 2020 18:57:33 |



US3532063

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:35:30

[Timepoint](#)

| Audit                                              | User                              | Time (GMT)           |
|----------------------------------------------------|-----------------------------------|----------------------|
| User accepted default value 'Post-Dose (POSTDOSE)' | Kathy Stephens (b) (4)<br>(b) (4) | 22 Aug 2020 18:32:27 |

US3532063

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:35:30

[Were vital signs assessed?](#)

| Audit                                                                                  | User                              | Time (GMT)           |
|----------------------------------------------------------------------------------------|-----------------------------------|----------------------|
| User closed query 'Data is required. Please complete.' (Site from System).             | System                            | 22 Aug 2020 18:34:43 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System                            | 22 Aug 2020 18:34:43 |
| User entered 'Yes (Y)' reason for change: Data Entry Error                             | Kathy Stephens (b) (4)<br>(b) (4) | 22 Aug 2020 18:34:43 |
| User opened query 'Data is required. Please complete.' (Site from System).             | System                            | 22 Aug 2020 18:32:27 |
| User entered empty.                                                                    | Kathy Stephens (b) (4)<br>(b) (4) | 22 Aug 2020 18:32:27 |

US3532063

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:35:30

Date of assessment (*dd MMM yyyy*)

| Audit                                                          | User                   | Time (GMT)           |
|----------------------------------------------------------------|------------------------|----------------------|
| User entered '18 Aug 2020' reason for change: Data Entry Error | Kathy Stephens (b) (4) | 22 Aug 2020 18:34:43 |
| User entered empty.                                            | Kathy Stephens (b) (4) | 22 Aug 2020 18:32:27 |

US3532063

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:35:30

Time of assessment (00:00-23:59)

| Audit                                                    | User                   | Time (GMT)           |
|----------------------------------------------------------|------------------------|----------------------|
| User entered '15:20' reason for change: Data Entry Error | Kathy Stephens (b) (4) | 22 Aug 2020 18:34:43 |
| User entered empty.                                      | Kathy Stephens (b) (4) | 22 Aug 2020 18:32:27 |

US3532063

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 09:35:30**

[Vital Signs Date and Time \(derived\)](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '18 Aug 2020 15:20' | System | 22 Aug 2020 18:34:43 |
| User entered empty.              | System | 22 Aug 2020 18:32:27 |

US3532063

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:35:30

Temperature (xxx.x)

| Audit                                                                                   | User                   | Time (GMT)           |
|-----------------------------------------------------------------------------------------|------------------------|----------------------|
| User closed query 'Data entered is non-conformant. Please correct.' (Site from System). | System                 | 22 Aug 2020 18:35:03 |
| User entered '97.4' F reason for change: Data Entry Error                               | Kathy Stephens (b) (4) | 22 Aug 2020 18:35:03 |
| User opened query 'Data entered is non-conformant. Please correct.' (Site from System). | System                 | 22 Aug 2020 18:34:43 |
| User entered '97.4' (non-conformant).                                                   | Kathy Stephens (b) (4) | 22 Aug 2020 18:34:43 |
| User entered empty.                                                                     | Kathy Stephens (b) (4) | 22 Aug 2020 18:32:27 |

US3532063

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:35:30

[Route of measurement](#)

| Audit                                                          | User                   | Time (GMT)           |
|----------------------------------------------------------------|------------------------|----------------------|
| User entered 'Oral (Oral)' reason for change: Data Entry Error | Kathy Stephens (b) (4) | 22 Aug 2020 18:34:43 |
| User entered empty.                                            | Kathy Stephens (b) (4) | 22 Aug 2020 18:32:27 |

US3532063

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:35:30

[If Other, specify](#)

| Audit               | User                              | Time (GMT)           |
|---------------------|-----------------------------------|----------------------|
| User entered empty. | Kathy Stephens (b) (4)<br>(b) (4) | 22 Aug 2020 18:32:27 |



US3532063

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:35:30

[Pulse \(xxx\)](#)

| Audit                                                 | User                   | Time (GMT)           |
|-------------------------------------------------------|------------------------|----------------------|
| User entered '65' reason for change: Data Entry Error | Kathy Stephens (b) (4) | 22 Aug 2020 18:34:43 |
| User entered empty.                                   | Kathy Stephens (b) (4) | 22 Aug 2020 18:32:27 |

US3532063

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 09:35:30**

[Pulse units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'bpm'  | System | 22 Aug 2020 18:34:43 |
| User entered empty. | System | 22 Aug 2020 18:32:27 |

US3532063

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:35:30

[Respiratory Rate \(xxx\)](#)

| Audit                                                 | User                   | Time (GMT)           |
|-------------------------------------------------------|------------------------|----------------------|
| User entered '18' reason for change: Data Entry Error | Kathy Stephens (b) (4) | 22 Aug 2020 18:34:43 |
| User entered empty.                                   | Kathy Stephens (b) (4) | 22 Aug 2020 18:32:27 |

US3532063

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 09:35:30**

[Respiratory Rate units](#)

| Audit                      | User   | Time (GMT)           |
|----------------------------|--------|----------------------|
| User entered 'breaths/min' | System | 22 Aug 2020 18:34:43 |
| User entered empty.        | System | 22 Aug 2020 18:32:27 |

US3532063

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:35:30

Systolic Blood Pressure (xxx)

| Audit                                                  | User                   | Time (GMT)           |
|--------------------------------------------------------|------------------------|----------------------|
| User entered '115' reason for change: Data Entry Error | Kathy Stephens (b) (4) | 22 Aug 2020 18:34:43 |
| User entered empty.                                    | Kathy Stephens (b) (4) | 22 Aug 2020 18:32:27 |

US3532063

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 09:35:30**

[Systolic Blood Pressure units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 22 Aug 2020 18:34:43 |
| User entered empty. | System | 22 Aug 2020 18:32:27 |

US3532063

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:35:30

[Diastolic Blood Pressure \(xxx\)](#)

| Audit                                                 | User                   | Time (GMT)           |
|-------------------------------------------------------|------------------------|----------------------|
| User entered '76' reason for change: Data Entry Error | Kathy Stephens (b) (4) | 22 Aug 2020 18:34:43 |
| User entered empty.                                   | Kathy Stephens (b) (4) | 22 Aug 2020 18:32:27 |

US3532063

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:35:30

[Diastolic Blood Pressure units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 22 Aug 2020 18:34:43 |
| User entered empty. | System | 22 Aug 2020 18:32:27 |



US3532063

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 09:35:30

Was the physical examination performed?

| Audit                  | User                              | Time (GMT)           |
|------------------------|-----------------------------------|----------------------|
| User entered 'Yes (Y)' | Kathy Stephens (b) (4)<br>(b) (4) | 18 Aug 2020 18:57:45 |

US3532063

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 09:35:30

Date of examination (*dd MMM yyyy*)

| Audit                      | User                              | Time (GMT)           |
|----------------------------|-----------------------------------|----------------------|
| User entered '18 Aug 2020' | Kathy Stephens (b) (4)<br>(b) (4) | 18 Aug 2020 18:57:45 |

US3532063

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:35:30

[Was study treatment given?](#)

| Audit                  | User                              | Time (GMT)           |
|------------------------|-----------------------------------|----------------------|
| User entered 'Yes (Y)' | Kathy Stephens (b) (4)<br>(b) (4) | 18 Aug 2020 18:58:25 |

US3532063

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:35:30

If No, reason not given

| Audit               | User                              | Time (GMT)           |
|---------------------|-----------------------------------|----------------------|
| User entered empty. | Kathy Stephens (b) (4)<br>(b) (4) | 18 Aug 2020 18:58:25 |

US3532063

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 26 Nov 2020 09:35:30**

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

| Audit               | User                              | Time (GMT)           |
|---------------------|-----------------------------------|----------------------|
| User entered empty. | Kathy Stephens (b) (4)<br>(b) (4) | 18 Aug 2020 18:58:25 |

US3532063

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 26 Nov 2020 09:35:30**

[What was the study treatment?](#)

| Audit                               | User   | Time (GMT)           |
|-------------------------------------|--------|----------------------|
| User entered 'MRNA-1273 OR PLACEBO' | System | 18 Aug 2020 18:58:25 |

US3532063

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:35:30

What was the treatment date? (dd MMM yyyy)

| Audit                      | User                              | Time (GMT)           |
|----------------------------|-----------------------------------|----------------------|
| User entered '18 Aug 2020' | Kathy Stephens (b) (4)<br>(b) (4) | 18 Aug 2020 18:58:25 |

US3532063

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:35:30

[What was the treatment time? \(00:00-23:59\)](#)

| Audit                | User                              | Time (GMT)           |
|----------------------|-----------------------------------|----------------------|
| User entered '14:41' | Kathy Stephens (b) (4)<br>(b) (4) | 18 Aug 2020 18:58:25 |



US3532063

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 26 Nov 2020 09:35:30**

[Treatment Date and Time \(derived\)](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '18 Aug 2020 14:41' | System | 18 Aug 2020 18:58:25 |

US3532063

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:35:30

[Which arm was used to give treatment?](#)

| Audit                              | User                              | Time (GMT)           |
|------------------------------------|-----------------------------------|----------------------|
| User entered 'Left Arm (LEFT ARM)' | Kathy Stephens (b) (4)<br>(b) (4) | 18 Aug 2020 18:58:25 |

US3532063

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 26 Nov 2020 09:35:30**

[What was the frequency of the study treatment dosing?](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'ONCE' | System | 18 Aug 2020 18:58:25 |

US3532063

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 26 Nov 2020 09:35:30**

[What was the route of administration for the study treatment?](#)

| Audit                        | User   | Time (GMT)           |
|------------------------------|--------|----------------------|
| User entered 'INTRAMUSCULAR' | System | 18 Aug 2020 18:58:25 |

US3532063

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 26 Nov 2020 09:35:30**

[Was the sample collected?](#)

| Audit                  | User                              | Time (GMT)           |
|------------------------|-----------------------------------|----------------------|
| User entered 'Yes (Y)' | Kathy Stephens (b) (4)<br>(b) (4) | 18 Aug 2020 18:59:16 |

US3532063

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:35:30

Collection date (*dd MMM yyyy*)

| Audit                      | User                              | Time (GMT)           |
|----------------------------|-----------------------------------|----------------------|
| User entered '18 Aug 2020' | Kathy Stephens (b) (4)<br>(b) (4) | 18 Aug 2020 18:59:16 |

US3532063

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 26 Nov 2020 09:35:30**

[Collection time \(00:00-23:59\)](#)

| Audit                | User                              | Time (GMT)           |
|----------------------|-----------------------------------|----------------------|
| User entered '14:21' | Kathy Stephens (b) (4)<br>(b) (4) | 18 Aug 2020 18:59:16 |

US3532063

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 26 Nov 2020 09:35:30**

[Collection date and time \(derived\)](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '18 Aug 2020 14:21' | System | 18 Aug 2020 18:59:16 |



US3532063

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:35:30

Collection date (*dd MMM yyyy*)

| Audit                      | User                              | Time (GMT)           |
|----------------------------|-----------------------------------|----------------------|
| User entered '18 Aug 2020' | Kathy Stephens (b) (4)<br>(b) (4) | 18 Aug 2020 19:00:09 |

US3532063

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:35:30

[Lab Test](#)

| Audit                                                        | User                   | Time (GMT)           |
|--------------------------------------------------------------|------------------------|----------------------|
| User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)' | Kathy Stephens (b) (4) | 18 Aug 2020 19:00:09 |

US3532063

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:35:30

[Was the sample collected?](#)

| Audit                  | User                              | Time (GMT)           |
|------------------------|-----------------------------------|----------------------|
| User entered 'Yes (Y)' | Kathy Stephens (b) (4)<br>(b) (4) | 18 Aug 2020 19:00:09 |

US3532063

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 26 Nov 2020 09:35:30**

[Collection time \(00:00 - 23:59\)](#)

| Audit                | User                              | Time (GMT)           |
|----------------------|-----------------------------------|----------------------|
| User entered '14:11' | Kathy Stephens (b) (4)<br>(b) (4) | 18 Aug 2020 19:00:09 |

US3532063

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 26 Nov 2020 09:35:30**

[Collection date and time \(derived\)](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '18 Aug 2020 14:11' | System | 18 Aug 2020 19:00:09 |

US3532063

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:35:30

[Lab Test](#)

| Audit                                                        | User                   | Time (GMT)           |
|--------------------------------------------------------------|------------------------|----------------------|
| User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)' | Kathy Stephens (b) (4) | 18 Aug 2020 19:00:09 |

US3532063

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:35:30

[Was the sample collected?](#)

| Audit                 | User                              | Time (GMT)           |
|-----------------------|-----------------------------------|----------------------|
| User entered 'No (N)' | Kathy Stephens (b) (4)<br>(b) (4) | 18 Aug 2020 19:00:09 |

US3532063

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:35:30

Collection time (00:00 - 23:59)

| Audit               | User                              | Time (GMT)           |
|---------------------|-----------------------------------|----------------------|
| User entered empty. | Kathy Stephens (b) (4)<br>(b) (4) | 18 Aug 2020 19:00:09 |



US3532063

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 26 Nov 2020 09:35:30**

[Collection date and time \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 18 Aug 2020 19:00:09 |

US3532063

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 09:35:30

[Is the participant continuing to the next visit?](#)

| Audit                  | User                              | Time (GMT)           |
|------------------------|-----------------------------------|----------------------|
| User entered 'Yes (Y)' | Kathy Stephens (b) (4)<br>(b) (4) | 22 Aug 2020 18:35:40 |

US3532063

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 26 Nov 2020 09:35:30**

[Continuing Flag](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 22 Aug 2020 18:35:40 |

US3532063

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 26 Nov 2020 09:35:30

**TIMEPOINT**

| Audit                                                                | User   | Time (GMT)           |
|----------------------------------------------------------------------|--------|----------------------|
| Data entry locked.                                                   | System | 18 Aug 2020 18:58:25 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 18 Aug 2020 18:58:25 |

US3532063

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 26 Nov 2020 09:35:30

Was **TEMPERATURE** taken?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-18T15:21:30', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '56dec1b9-4e6e-44c1-8552-48d9c3434436' | System | 18 Aug 2020 19:21:56 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                                         | System | 18 Aug 2020 19:21:56 |

US3532063

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 26 Nov 2020 09:35:30

Please record your **TEMPERATURE** in °F

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-18T15:21:41', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '56dec1b9-4e6e-44c1-8552-48d9c3434436' | System | 18 Aug 2020 19:21:56 |
| User entered '97.5'                                                                                                                                                                                                                                            | System | 18 Aug 2020 19:21:56 |

US3532063

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 26 Nov 2020 09:35:30

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

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-18T15:21:45', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '56dec1b9-4e6e-44c1-8552-48d9c3434436' | System | 18 Aug 2020 19:21:56 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 18 Aug 2020 19:21:56 |

US3532063

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 26 Nov 2020 09:35:30

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-18T15:21:51', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '56dec1b9-4e6e-44c1-8552-48d9c3434436' | System | 18 Aug 2020 19:21:56 |
| User entered '18 Aug 2020 15:21'                                                                                                                                                                                                                               | System | 18 Aug 2020 19:21:56 |



US3532063

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 26 Nov 2020 09:35:30**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '18 Aug 2020 15:01' | System | 18 Aug 2020 18:58:25 |

US3532063

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 26 Nov 2020 09:35:30**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '18 Aug 2020 17:31' | System | 18 Aug 2020 18:58:25 |

US3532063

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 26 Nov 2020 09:35:30

**TIMEPOINT**

| Audit                                             | User   | Time (GMT)           |
|---------------------------------------------------|--------|----------------------|
| Data entry locked.                                | System | 18 Aug 2020 18:58:25 |
| User entered 'Day 1, after vaccination (at home)' | System | 18 Aug 2020 18:58:25 |

US3532063

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 26 Nov 2020 09:35:30

Was **TEMPERATURE** taken?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-18T21:14:03', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'b2614d4c-03bb-4402-b251-72569e616644' | System | 19 Aug 2020 01:15:43 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                                         | System | 19 Aug 2020 01:15:43 |

US3532063

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 26 Nov 2020 09:35:30

Please record your **TEMPERATURE** in °F

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-18T21:15:16', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'b2614d4c-03bb-4402-b251-72569e616644' | System | 19 Aug 2020 01:15:43 |
| User entered '96.8'                                                                                                                                                                                                                                            | System | 19 Aug 2020 01:15:43 |

US3532063

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 26 Nov 2020 09:35:30

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

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-18T21:15:25', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'b2614d4c-03bb-4402-b251-72569e616644' | System | 19 Aug 2020 01:15:43 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 19 Aug 2020 01:15:43 |

US3532063

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 26 Nov 2020 09:35:30

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-18T21:15:40', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'b2614d4c-03bb-4402-b251-72569e616644' | System | 19 Aug 2020 01:15:43 |
| User entered '18 Aug 2020 21:15'                                                                                                                                                                                                                               | System | 19 Aug 2020 01:15:43 |

US3532063

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 26 Nov 2020 09:35:30**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '18 Aug 2020 18:26' | System | 18 Aug 2020 18:58:25 |



US3532063

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 26 Nov 2020 09:35:30**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '19 Aug 2020 11:59' | System | 18 Aug 2020 18:58:25 |

US3532063

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 09:35:30

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 18 Aug 2020 18:58:25 |
| User entered 'Day 2' | System | 18 Aug 2020 18:58:25 |

US3532063

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 09:35:30

Was **TEMPERATURE** taken?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-19T21:18:09', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '7e2327df-4234-44d9-a0c3-af249d3e3277' | System | 20 Aug 2020 01:18:52 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                                         | System | 20 Aug 2020 01:18:52 |

US3532063

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 09:35:30

Please record your **TEMPERATURE** in °F

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-19T21:18:33', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '7e2327df-4234-44d9-a0c3-af249d3e3277' | System | 20 Aug 2020 01:18:52 |
| User entered '97.5'                                                                                                                                                                                                                                            | System | 20 Aug 2020 01:18:52 |

US3532063

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 09:35:30

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

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-19T21:18:37', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '7e2327df-4234-44d9-a0c3-af249d3e3277' | System | 20 Aug 2020 01:18:52 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 20 Aug 2020 01:18:52 |

US3532063

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 26 Nov 2020 09:35:30**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-19T21:18:51', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '7e2327df-4234-44d9-a0c3-af249d3e3277' | System | 20 Aug 2020 01:18:52 |
| User entered '19 Aug 2020 21:18'                                                                                                                                                                                                                               | System | 20 Aug 2020 01:18:52 |

US3532063

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 26 Nov 2020 09:35:30**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '19 Aug 2020 12:00' | System | 18 Aug 2020 18:58:25 |

US3532063

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 26 Nov 2020 09:35:30**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '20 Aug 2020 11:59' | System | 18 Aug 2020 18:58:25 |



US3532063

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 26 Nov 2020 09:35:30

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 18 Aug 2020 18:58:25 |
| User entered 'Day 3' | System | 18 Aug 2020 18:58:25 |

US3532063

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 26 Nov 2020 09:35:30

Was **TEMPERATURE** taken?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-20T20:05:44', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '041b35b0-f674-4e13-9775-1645c837d90f' | System | 21 Aug 2020 00:06:07 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                                         | System | 21 Aug 2020 00:06:07 |

US3532063

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 26 Nov 2020 09:35:30

Please record your **TEMPERATURE** in °F

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-20T20:05:52', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '041b35b0-f674-4e13-9775-1645c837d90f' | System | 21 Aug 2020 00:06:07 |
| User entered '97.7'                                                                                                                                                                                                                                            | System | 21 Aug 2020 00:06:07 |

US3532063

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 26 Nov 2020 09:35:30

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

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-20T20:05:55', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '041b35b0-f674-4e13-9775-1645c837d90f' | System | 21 Aug 2020 00:06:07 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 21 Aug 2020 00:06:07 |

US3532063

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 26 Nov 2020 09:35:30

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-20T20:06:04', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '041b35b0-f674-4e13-9775-1645c837d90f' | System | 21 Aug 2020 00:06:07 |
| User entered '20 Aug 2020 20:06'                                                                                                                                                                                                                               | System | 21 Aug 2020 00:06:07 |

US3532063

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 26 Nov 2020 09:35:30**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '20 Aug 2020 12:00' | System | 18 Aug 2020 18:58:25 |

US3532063

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 26 Nov 2020 09:35:30**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '21 Aug 2020 11:59' | System | 18 Aug 2020 18:58:25 |

US3532063

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 09:35:30

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 18 Aug 2020 18:58:25 |
| User entered 'Day 4' | System | 18 Aug 2020 18:58:25 |



US3532063

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 09:35:30

Was **TEMPERATURE** taken?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-21T22:02:28', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '8d668f3d-0f67-4685-a30d-1d63eead02f2' | System | 22 Aug 2020 02:02:57 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                                         | System | 22 Aug 2020 02:02:57 |

US3532063

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 09:35:30

Please record your **TEMPERATURE** in °F

| Audit                                                                                                                                                                                                                                                         | User   | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-21T22:02:45', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '8d668f3d-0f67-4685-a30d-1d63ead02f2' | System | 22 Aug 2020 02:02:57 |
| User entered '97.5'                                                                                                                                                                                                                                           | System | 22 Aug 2020 02:02:57 |

US3532063

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 09:35:30

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

| Audit                                                                                                                                                                                                                                                         | User   | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-21T22:02:48', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '8d668f3d-0f67-4685-a30d-1d63ead02f2' | System | 22 Aug 2020 02:02:57 |
| User entered 'No (N)'                                                                                                                                                                                                                                         | System | 22 Aug 2020 02:02:57 |

US3532063

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 26 Nov 2020 09:35:30**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-21T22:02:53', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '8d668f3d-0f67-4685-a30d-1d63eead02f2' | System | 22 Aug 2020 02:02:57 |
| User entered '21 Aug 2020 22:02'                                                                                                                                                                                                                               | System | 22 Aug 2020 02:02:57 |

US3532063

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 26 Nov 2020 09:35:30**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '21 Aug 2020 12:00' | System | 18 Aug 2020 18:58:25 |

US3532063

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 26 Nov 2020 09:35:30**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '22 Aug 2020 11:59' | System | 18 Aug 2020 18:58:25 |

US3532063

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 26 Nov 2020 09:35:30

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 18 Aug 2020 18:58:25 |
| User entered 'Day 5' | System | 18 Aug 2020 18:58:25 |

US3532063

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 26 Nov 2020 09:35:30

Was **TEMPERATURE** taken?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-22T21:26:50', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'eb05bc54-a303-47e7-a8c4-39f482e7439f' | System | 23 Aug 2020 01:27:25 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                                         | System | 23 Aug 2020 01:27:25 |



US3532063

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 26 Nov 2020 09:35:30

Please record your **TEMPERATURE** in °F

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-22T21:27:14', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'eb05bc54-a303-47e7-a8c4-39f482e7439f' | System | 23 Aug 2020 01:27:25 |
| User entered '96.2'                                                                                                                                                                                                                                            | System | 23 Aug 2020 01:27:25 |

US3532063

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 26 Nov 2020 09:35:30

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

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-22T21:27:17', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'eb05bc54-a303-47e7-a8c4-39f482e7439f' | System | 23 Aug 2020 01:27:25 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 23 Aug 2020 01:27:25 |

US3532063

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 26 Nov 2020 09:35:30

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-22T21:27:22', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'eb05bc54-a303-47e7-a8c4-39f482e7439f' | System | 23 Aug 2020 01:27:25 |
| User entered '22 Aug 2020 21:27'                                                                                                                                                                                                                               | System | 23 Aug 2020 01:27:25 |

US3532063

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 26 Nov 2020 09:35:30**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '22 Aug 2020 12:00' | System | 18 Aug 2020 18:58:25 |

US3532063

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 26 Nov 2020 09:35:30**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '23 Aug 2020 11:59' | System | 18 Aug 2020 18:58:25 |

US3532063

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 26 Nov 2020 09:35:30

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 18 Aug 2020 18:58:25 |
| User entered 'Day 6' | System | 18 Aug 2020 18:58:25 |

US3532063

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 26 Nov 2020 09:35:30

Was **TEMPERATURE** taken?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-23T21:28:14', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'a4994578-ba70-47bc-ae12-bc9f70386258' | System | 24 Aug 2020 01:28:42 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                                         | System | 24 Aug 2020 01:28:42 |

US3532063

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 26 Nov 2020 09:35:30

Please record your **TEMPERATURE** in °F

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-23T21:28:20', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'a4994578-ba70-47bc-ae12-bc9f70386258' | System | 24 Aug 2020 01:28:42 |
| User entered '96.7'                                                                                                                                                                                                                                            | System | 24 Aug 2020 01:28:42 |



US3532063

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 26 Nov 2020 09:35:30

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

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-23T21:28:23', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'a4994578-ba70-47bc-ae12-bc9f70386258' | System | 24 Aug 2020 01:28:42 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 24 Aug 2020 01:28:42 |

US3532063

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 26 Nov 2020 09:35:30**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-23T21:28:28', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'a4994578-ba70-47bc-ae12-bc9f70386258' | System | 24 Aug 2020 01:28:42 |
| User entered '23 Aug 2020 21:28'                                                                                                                                                                                                                               | System | 24 Aug 2020 01:28:42 |

US3532063

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 26 Nov 2020 09:35:30**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '23 Aug 2020 12:00' | System | 18 Aug 2020 18:58:25 |

US3532063

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 26 Nov 2020 09:35:30**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '24 Aug 2020 11:59' | System | 18 Aug 2020 18:58:25 |

US3532063

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 26 Nov 2020 09:35:30

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 18 Aug 2020 18:58:25 |
| User entered 'Day 7' | System | 18 Aug 2020 18:58:25 |

US3532063

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 26 Nov 2020 09:35:30

Was **TEMPERATURE** taken?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-25T01:14:46', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '93bf4a70-d818-41d0-b7bc-7b5a449e6739' | System | 25 Aug 2020 05:15:04 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                                         | System | 25 Aug 2020 05:15:04 |

US3532063

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 26 Nov 2020 09:35:30

Please record your **TEMPERATURE** in °F

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-25T01:14:53', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '93bf4a70-d818-41d0-b7bc-7b5a449e6739' | System | 25 Aug 2020 05:15:04 |
| User entered '96.8'                                                                                                                                                                                                                                            | System | 25 Aug 2020 05:15:04 |

US3532063

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 26 Nov 2020 09:35:30

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

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-25T01:14:56', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '93bf4a70-d818-41d0-b7bc-7b5a449e6739' | System | 25 Aug 2020 05:15:04 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 25 Aug 2020 05:15:04 |



US3532063

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 26 Nov 2020 09:35:30

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-25T01:15:01', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '93bf4a70-d818-41d0-b7bc-7b5a449e6739' | System | 25 Aug 2020 05:15:04 |
| User entered '25 Aug 2020 01:15'                                                                                                                                                                                                                               | System | 25 Aug 2020 05:15:04 |

US3532063

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 26 Nov 2020 09:35:30**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '24 Aug 2020 12:00' | System | 18 Aug 2020 18:58:25 |

US3532063

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 26 Nov 2020 09:35:30**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '25 Aug 2020 11:59' | System | 18 Aug 2020 18:58:25 |

US3532063

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 09:35:30

**TIMEPOINT**

| Audit                                                                | User   | Time (GMT)           |
|----------------------------------------------------------------------|--------|----------------------|
| Data entry locked.                                                   | System | 18 Aug 2020 18:58:25 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 18 Aug 2020 18:58:25 |

US3532063

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 09:35:30

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 (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-18T15:22:10', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '3564b664-7c04-4309-8604-0ec030e0b770' | System | 18 Aug 2020 19:23:03 |
| User entered 'None (1)'                                                                                                                                                                                                                                        | System | 18 Aug 2020 19:23:03 |

US3532063

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 09:35:30

Is there any REDNESS AT INJECTION SITE?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-18T15:22:26', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '3564b664-7c04-4309-8604-0ec030e0b770' | System | 18 Aug 2020 19:23:03 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 18 Aug 2020 19:23:03 |

US3532063

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 09:35:30

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

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-18T15:22:35', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '3564b664-7c04-4309-8604-0ec030e0b770' | System | 18 Aug 2020 19:23:03 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 18 Aug 2020 19:23:03 |

US3532063

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 09:35:30

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 (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-18T15:22:43', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '3564b664-7c04-4309-8604-0ec030e0b770' | System | 18 Aug 2020 19:23:03 |
| User entered 'None (1)'                                                                                                                                                                                                                                        | System | 18 Aug 2020 19:23:03 |



US3532063

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 09:35:30**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-18T15:22:48', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '3564b664-7c04-4309-8604-0ec030e0b770' | System | 18 Aug 2020 19:23:03 |
| User entered '18 Aug 2020 15:22'                                                                                                                                                                                                                               | System | 18 Aug 2020 19:23:03 |

US3532063

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 09:35:30**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '18 Aug 2020 15:01' | System | 18 Aug 2020 18:58:25 |

US3532063

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 09:35:30**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '18 Aug 2020 17:31' | System | 18 Aug 2020 18:58:25 |

US3532063

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 26 Nov 2020 09:35:30

**TIMEPOINT**

| Audit                                             | User   | Time (GMT)           |
|---------------------------------------------------|--------|----------------------|
| Data entry locked.                                | System | 18 Aug 2020 18:58:25 |
| User entered 'Day 1, after vaccination (at home)' | System | 18 Aug 2020 18:58:25 |

US3532063

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 26 Nov 2020 09:35:30

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 (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-18T21:15:54', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'd16d7c2b-dbd1-4a0c-9a02-33deb4cb44d8' | System | 19 Aug 2020 01:16:58 |
| User entered 'None (1)'                                                                                                                                                                                                                                        | System | 19 Aug 2020 01:16:58 |

US3532063

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 26 Nov 2020 09:35:30

Is there any REDNESS AT INJECTION SITE?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-18T21:16:22', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'd16d7c2b-dbd1-4a0c-9a02-33deb4cb44d8' | System | 19 Aug 2020 01:16:58 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 19 Aug 2020 01:16:58 |

US3532063

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 26 Nov 2020 09:35:30

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

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-18T21:16:28', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'd16d7c2b-dbd1-4a0c-9a02-33deb4cb44d8' | System | 19 Aug 2020 01:16:58 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 19 Aug 2020 01:16:58 |

US3532063

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 26 Nov 2020 09:35:30

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 (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-18T21:16:48', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'd16d7c2b-dbd1-4a0c-9a02-33deb4cb44d8' | System | 19 Aug 2020 01:16:58 |
| User entered 'None (1)'                                                                                                                                                                                                                                        | System | 19 Aug 2020 01:16:58 |



US3532063

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 26 Nov 2020 09:35:30

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-18T21:16:56', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'd16d7c2b-dbd1-4a0c-9a02-33deb4cb44d8' | System | 19 Aug 2020 01:16:58 |
| User entered '18 Aug 2020 21:16'                                                                                                                                                                                                                               | System | 19 Aug 2020 01:16:58 |

US3532063

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 09:35:30**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '18 Aug 2020 18:26' | System | 18 Aug 2020 18:58:25 |

US3532063

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 09:35:30**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '19 Aug 2020 11:59' | System | 18 Aug 2020 18:58:25 |

US3532063

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 26 Nov 2020 09:35:30

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 18 Aug 2020 18:58:25 |
| User entered 'Day 2' | System | 18 Aug 2020 18:58:25 |

US3532063

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 26 Nov 2020 09:35:30

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 (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-19T21:18:59', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '9e31483d-0892-4e15-b862-6d050a627f1c' | System | 20 Aug 2020 01:19:51 |
| User entered 'None (1)'                                                                                                                                                                                                                                        | System | 20 Aug 2020 01:19:51 |

US3532063

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 26 Nov 2020 09:35:30

Is there any REDNESS AT INJECTION SITE?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-19T21:19:29', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '9e31483d-0892-4e15-b862-6d050a627f1c' | System | 20 Aug 2020 01:19:51 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 20 Aug 2020 01:19:51 |

US3532063

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 26 Nov 2020 09:35:30

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

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-19T21:19:34', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '9e31483d-0892-4e15-b862-6d050a627f1c' | System | 20 Aug 2020 01:19:51 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 20 Aug 2020 01:19:51 |

US3532063

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 26 Nov 2020 09:35:30

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 (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-19T21:19:42', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '9e31483d-0892-4e15-b862-6d050a627f1c' | System | 20 Aug 2020 01:19:51 |
| User entered 'None (1)'                                                                                                                                                                                                                                        | System | 20 Aug 2020 01:19:51 |



US3532063

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 09:35:30**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-19T21:19:47', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '9e31483d-0892-4e15-b862-6d050a627f1c' | System | 20 Aug 2020 01:19:51 |
| User entered '19 Aug 2020 21:19'                                                                                                                                                                                                                               | System | 20 Aug 2020 01:19:51 |

US3532063

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 09:35:30**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '19 Aug 2020 12:00' | System | 18 Aug 2020 18:58:25 |

US3532063

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 09:35:30**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '20 Aug 2020 11:59' | System | 18 Aug 2020 18:58:25 |

US3532063

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 26 Nov 2020 09:35:30

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 18 Aug 2020 18:58:25 |
| User entered 'Day 3' | System | 18 Aug 2020 18:58:25 |

US3532063

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 26 Nov 2020 09:35:30

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 (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-20T20:08:24', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '82705051-cf35-44b1-b648-3466e6be7617' | System | 21 Aug 2020 00:08:38 |
| User entered 'None (1)'                                                                                                                                                                                                                                        | System | 21 Aug 2020 00:08:38 |

US3532063

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 26 Nov 2020 09:35:30

Is there any REDNESS AT INJECTION SITE?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-20T20:06:17', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '82705051-cf35-44b1-b648-3466e6be7617' | System | 21 Aug 2020 00:08:38 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 21 Aug 2020 00:08:38 |

US3532063

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 26 Nov 2020 09:35:30

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

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-20T20:06:23', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '82705051-cf35-44b1-b648-3466e6be7617' | System | 21 Aug 2020 00:08:38 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                                         | System | 21 Aug 2020 00:08:38 |

US3532063

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 26 Nov 2020 09:35:30

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

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

| Audit                                                                                                                                                                                                                                                                           | User   | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-20T20:07:55', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '82705051-cf35-44b1-b648-3466e6be7617' User entered '8' | System | 21 Aug 2020 00:08:38 |
|                                                                                                                                                                                                                                                                                 | System | 21 Aug 2020 00:08:38 |



US3532063

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 26 Nov 2020 09:35:30

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 (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-20T20:08:10', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '82705051-cf35-44b1-b648-3466e6be7617' | System | 21 Aug 2020 00:08:38 |
| User entered 'Does not interfere with activity (2)'                                                                                                                                                                                                            | System | 21 Aug 2020 00:08:38 |

US3532063

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 09:35:30**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-20T20:08:32', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '82705051-cf35-44b1-b648-3466e6be7617' | System | 21 Aug 2020 00:08:38 |
| User entered '20 Aug 2020 20:08'                                                                                                                                                                                                                               | System | 21 Aug 2020 00:08:38 |

US3532063

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 09:35:30**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '20 Aug 2020 12:00' | System | 18 Aug 2020 18:58:25 |

US3532063

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 09:35:30**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '21 Aug 2020 11:59' | System | 18 Aug 2020 18:58:25 |

US3532063

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 26 Nov 2020 09:35:30

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 18 Aug 2020 18:58:25 |
| User entered 'Day 4' | System | 18 Aug 2020 18:58:25 |

US3532063

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 26 Nov 2020 09:35:30

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 (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-21T22:04:00', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '1f7a768c-7576-4589-bf41-3af83c7518fc' | System | 22 Aug 2020 02:04:28 |
| User entered 'None (1)'                                                                                                                                                                                                                                        | System | 22 Aug 2020 02:04:28 |

US3532063

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 26 Nov 2020 09:35:30

Is there any REDNESS AT INJECTION SITE?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-21T22:04:07', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '1f7a768c-7576-4589-bf41-3af83c7518fc' | System | 22 Aug 2020 02:04:28 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 22 Aug 2020 02:04:28 |

US3532063

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 26 Nov 2020 09:35:30

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

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-21T22:04:15', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '1f7a768c-7576-4589-bf41-3af83c7518fc' | System | 22 Aug 2020 02:04:28 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 22 Aug 2020 02:04:28 |



US3532063

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 26 Nov 2020 09:35:30

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 (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-21T22:04:23', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '1f7a768c-7576-4589-bf41-3af83c7518fc' | System | 22 Aug 2020 02:04:28 |
| User entered 'None (1)'                                                                                                                                                                                                                                        | System | 22 Aug 2020 02:04:28 |

US3532063

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 09:35:30**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-21T22:04:26', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '1f7a768c-7576-4589-bf41-3af83c7518fc' | System | 22 Aug 2020 02:04:28 |
| User entered '21 Aug 2020 22:04'                                                                                                                                                                                                                               | System | 22 Aug 2020 02:04:28 |

US3532063

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 09:35:30**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '21 Aug 2020 12:00' | System | 18 Aug 2020 18:58:25 |

US3532063

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 09:35:30**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '22 Aug 2020 11:59' | System | 18 Aug 2020 18:58:25 |

US3532063

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 26 Nov 2020 09:35:30

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 18 Aug 2020 18:58:25 |
| User entered 'Day 5' | System | 18 Aug 2020 18:58:25 |

US3532063

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 09:35:30**

[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 (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-22T21:27:28', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '989a15ea-8495-4a30-8b57-c4dab7041369' | System | 23 Aug 2020 01:28:53 |
| User entered 'None (1)'                                                                                                                                                                                                                                        | System | 23 Aug 2020 01:28:53 |

US3532063

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 26 Nov 2020 09:35:30

Is there any REDNESS AT INJECTION SITE?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-22T21:27:32', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '989a15ea-8495-4a30-8b57-c4dab7041369' | System | 23 Aug 2020 01:28:53 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 23 Aug 2020 01:28:53 |

US3532063

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 26 Nov 2020 09:35:30

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

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-22T21:28:37', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '989a15ea-8495-4a30-8b57-c4dab7041369' | System | 23 Aug 2020 01:28:53 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 23 Aug 2020 01:28:53 |



US3532063

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 26 Nov 2020 09:35:30

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 (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-22T21:28:43', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '989a15ea-8495-4a30-8b57-c4dab7041369' | System | 23 Aug 2020 01:28:53 |
| User entered 'None (1)'                                                                                                                                                                                                                                        | System | 23 Aug 2020 01:28:53 |

US3532063

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 09:35:30**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-22T21:28:47', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '989a15ea-8495-4a30-8b57-c4dab7041369' | System | 23 Aug 2020 01:28:53 |
| User entered '22 Aug 2020 21:28'                                                                                                                                                                                                                               | System | 23 Aug 2020 01:28:53 |

US3532063

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 09:35:30**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '22 Aug 2020 12:00' | System | 18 Aug 2020 18:58:25 |

US3532063

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 09:35:30**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '23 Aug 2020 11:59' | System | 18 Aug 2020 18:58:25 |

US3532063

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 26 Nov 2020 09:35:30

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 18 Aug 2020 18:58:25 |
| User entered 'Day 6' | System | 18 Aug 2020 18:58:25 |

US3532063

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 09:35:30**

[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 (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-23T21:28:33', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'abf08935-e688-4e27-af1f-644ba6c22a12' | System | 24 Aug 2020 01:29:58 |
| User entered 'None (1)'                                                                                                                                                                                                                                        | System | 24 Aug 2020 01:29:58 |

US3532063

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 26 Nov 2020 09:35:30

Is there any REDNESS AT INJECTION SITE?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-23T21:28:36', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'abf08935-e688-4e27-af1f-644ba6c22a12' | System | 24 Aug 2020 01:29:58 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 24 Aug 2020 01:29:58 |

US3532063

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 26 Nov 2020 09:35:30

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

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-23T21:28:50', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'abf08935-e688-4e27-af1f-644ba6c22a12' | System | 24 Aug 2020 01:29:58 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 24 Aug 2020 01:29:58 |



US3532063

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 26 Nov 2020 09:35:30

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 (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-23T21:28:56', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'abf08935-e688-4e27-af1f-644ba6c22a12' | System | 24 Aug 2020 01:29:58 |
| User entered 'None (1)'                                                                                                                                                                                                                                        | System | 24 Aug 2020 01:29:58 |

US3532063

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 09:35:30**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-23T21:28:59', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'abf08935-e688-4e27-af1f-644ba6c22a12' | System | 24 Aug 2020 01:29:58 |
| User entered '23 Aug 2020 21:28'                                                                                                                                                                                                                               | System | 24 Aug 2020 01:29:58 |

US3532063

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 09:35:30**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '23 Aug 2020 12:00' | System | 18 Aug 2020 18:58:25 |

US3532063

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 09:35:30**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '24 Aug 2020 11:59' | System | 18 Aug 2020 18:58:25 |

US3532063

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 26 Nov 2020 09:35:30

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 18 Aug 2020 18:58:25 |
| User entered 'Day 7' | System | 18 Aug 2020 18:58:25 |

US3532063

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 26 Nov 2020 09:35:30

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 (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-25T01:15:07', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'da13109b-245b-4d22-bc02-e84f0dcfec7' | System | 25 Aug 2020 05:15:25 |
| User entered 'None (1)'                                                                                                                                                                                                                                       | System | 25 Aug 2020 05:15:25 |

US3532063

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 26 Nov 2020 09:35:30

Is there any REDNESS AT INJECTION SITE?

| Audit                                                                                                                                                                                                                                                         | User   | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-25T01:15:10', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'da13109b-245b-4d22-bc02-e84f0dcfec7' | System | 25 Aug 2020 05:15:25 |
| User entered 'No (N)'                                                                                                                                                                                                                                         | System | 25 Aug 2020 05:15:25 |

US3532063

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 26 Nov 2020 09:35:30

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

| Audit                                                                                                                                                                                                                                                         | User   | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-25T01:15:13', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'da13109b-245b-4d22-bc02-e84f0dcfec7' | System | 25 Aug 2020 05:15:25 |
| User entered 'No (N)'                                                                                                                                                                                                                                         | System | 25 Aug 2020 05:15:25 |



US3532063

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 26 Nov 2020 09:35:30

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 (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-25T01:15:19', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'da13109b-245b-4d22-bc02-e84f0dcfec7' | System | 25 Aug 2020 05:15:25 |
| User entered 'None (1)'                                                                                                                                                                                                                                       | System | 25 Aug 2020 05:15:25 |

US3532063

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 09:35:30**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                         | User   | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-25T01:15:22', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'da13109b-245b-4d22-bc02-e84f0dcfec7' | System | 25 Aug 2020 05:15:25 |
| User entered '25 Aug 2020 01:15'                                                                                                                                                                                                                              | System | 25 Aug 2020 05:15:25 |

US3532063

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 09:35:30**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '24 Aug 2020 12:00' | System | 18 Aug 2020 18:58:25 |

US3532063

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 09:35:30**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '25 Aug 2020 11:59' | System | 18 Aug 2020 18:58:25 |

US3532063

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 09:35:30

**TIMEPOINT**

| Audit                                                                | User   | Time (GMT)           |
|----------------------------------------------------------------------|--------|----------------------|
| Data entry locked.                                                   | System | 18 Aug 2020 18:58:25 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 18 Aug 2020 18:58:25 |

US3532063

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 09:35:30

**HEADACHE**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-18T15:22:54', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'd187a012-952c-4028-b779-7e6d68218221' | System | 18 Aug 2020 19:23:21 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 18 Aug 2020 19:23:21 |

US3532063

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 09:35:30

**FATIGUE**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-18T15:22:57', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'd187a012-952c-4028-b779-7e6d68218221' | System | 18 Aug 2020 19:23:21 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 18 Aug 2020 19:23:21 |

US3532063

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 09:35:30

**MUSCLE ACHES ALL OVER BODY**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-18T15:23:00', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'd187a012-952c-4028-b779-7e6d68218221' | System | 18 Aug 2020 19:23:21 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 18 Aug 2020 19:23:21 |



US3532063

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 09:35:30

**JOINT ACHES IN SEVERAL JOINTS**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-18T15:23:03', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'd187a012-952c-4028-b779-7e6d68218221' | System | 18 Aug 2020 19:23:21 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 18 Aug 2020 19:23:21 |

US3532063

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 09:35:30

**NAUSEA/VOMITING**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-18T15:23:06', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'd187a012-952c-4028-b779-7e6d68218221' | System | 18 Aug 2020 19:23:21 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 18 Aug 2020 19:23:21 |

US3532063

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 09:35:30

**CHILLS**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-18T15:23:08', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'd187a012-952c-4028-b779-7e6d68218221' | System | 18 Aug 2020 19:23:21 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 18 Aug 2020 19:23:21 |

US3532063

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 09:35:30

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 (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-18T15:23:13', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'd187a012-952c-4028-b779-7e6d68218221' | System | 18 Aug 2020 19:23:21 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 18 Aug 2020 19:23:21 |

US3532063

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 09:35:30

[PC Time stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-18T15:23:19', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'd187a012-952c-4028-b779-7e6d68218221' | System | 18 Aug 2020 19:23:21 |
| User entered '18 Aug 2020 15:23'                                                                                                                                                                                                                               | System | 18 Aug 2020 19:23:21 |

US3532063

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 09:35:30**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '18 Aug 2020 15:01' | System | 18 Aug 2020 18:58:25 |

US3532063

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 09:35:30**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '18 Aug 2020 17:31' | System | 18 Aug 2020 18:58:25 |

US3532063

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 09:35:30

**TIMEPOINT**

| Audit                                             | User   | Time (GMT)           |
|---------------------------------------------------|--------|----------------------|
| Data entry locked.                                | System | 18 Aug 2020 18:58:25 |
| User entered 'Day 1, after vaccination (at home)' | System | 18 Aug 2020 18:58:25 |



US3532063

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 09:35:30

**HEADACHE**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-18T21:17:02', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'c8f48881-6bf6-40ba-bdc1-6653557fae2f' | System | 19 Aug 2020 01:17:48 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 19 Aug 2020 01:17:48 |

US3532063

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 09:35:30

**FATIGUE**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-18T21:17:16', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'c8f48881-6bf6-40ba-bdc1-6653557fae2f' | System | 19 Aug 2020 01:17:48 |
| User entered 'No interference with activity (1)'                                                                                                                                                                                                               | System | 19 Aug 2020 01:17:48 |

US3532063

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 09:35:30

**MUSCLE ACHES ALL OVER BODY**

| Audit                                                                                                                                                                                                                                                                                  | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-18T21:17:19', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'c8f48881-6bf6-40ba-bdc1-6653557fae2f' User entered 'None (0)' | System | 19 Aug 2020 01:17:48 |
|                                                                                                                                                                                                                                                                                        | System | 19 Aug 2020 01:17:48 |

US3532063

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 09:35:30

**JOINT ACHES IN SEVERAL JOINTS**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-18T21:17:23', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'c8f48881-6bf6-40ba-bdc1-6653557fae2f' | System | 19 Aug 2020 01:17:48 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 19 Aug 2020 01:17:48 |

US3532063

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 09:35:30

**NAUSEA/VOMITING**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-18T21:17:26', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'c8f48881-6bf6-40ba-bdc1-6653557fae2f' | System | 19 Aug 2020 01:17:48 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 19 Aug 2020 01:17:48 |

US3532063

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 09:35:30

**CHILLS**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-18T21:17:28', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'c8f48881-6bf6-40ba-bdc1-6653557fae2f' | System | 19 Aug 2020 01:17:48 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 19 Aug 2020 01:17:48 |

US3532063

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 09:35:30

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 (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-18T21:17:35', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'c8f48881-6bf6-40ba-bdc1-6653557fae2f' | System | 19 Aug 2020 01:17:48 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 19 Aug 2020 01:17:48 |

US3532063

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 09:35:30

[PC Time stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-18T21:17:45', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'c8f48881-6bf6-40ba-bdc1-6653557fae2f' | System | 19 Aug 2020 01:17:48 |
| User entered '18 Aug 2020 21:17'                                                                                                                                                                                                                               | System | 19 Aug 2020 01:17:48 |



US3532063

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 09:35:30**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '18 Aug 2020 18:26' | System | 18 Aug 2020 18:58:25 |

US3532063

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 09:35:30**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '19 Aug 2020 11:59' | System | 18 Aug 2020 18:58:25 |

US3532063

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 09:35:30

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 18 Aug 2020 18:58:25 |
| User entered 'Day 2' | System | 18 Aug 2020 18:58:25 |

US3532063

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 09:35:30

**HEADACHE**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-19T21:19:52', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '7723f06e-6935-4032-bfdb-313ed6d626e9' | System | 20 Aug 2020 01:20:30 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 20 Aug 2020 01:20:30 |

US3532063

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 09:35:30

**FATIGUE**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-19T21:19:57', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '7723f06e-6935-4032-bfdb-313ed6d626e9' | System | 20 Aug 2020 01:20:30 |
| User entered 'No interference with activity (1)'                                                                                                                                                                                                               | System | 20 Aug 2020 01:20:30 |

US3532063

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 09:35:30

**MUSCLE ACHES ALL OVER BODY**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-19T21:20:01', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '7723f06e-6935-4032-bfdb-313ed6d626e9' | System | 20 Aug 2020 01:20:30 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 20 Aug 2020 01:20:30 |

US3532063

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 09:35:30

**JOINT ACHES IN SEVERAL JOINTS**

| Audit                                                                                                                                                                                                                                                                                  | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-19T21:20:05', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '7723f06e-6935-4032-bfdb-313ed6d626e9' User entered 'None (0)' | System | 20 Aug 2020 01:20:30 |
|                                                                                                                                                                                                                                                                                        | System | 20 Aug 2020 01:20:30 |

US3532063

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 09:35:30

**NAUSEA/VOMITING**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-19T21:20:08', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '7723f06e-6935-4032-bfdb-313ed6d626e9' | System | 20 Aug 2020 01:20:30 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 20 Aug 2020 01:20:30 |



US3532063

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 09:35:30

**CHILLS**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-19T21:20:11', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '7723f06e-6935-4032-bfdb-313ed6d626e9' | System | 20 Aug 2020 01:20:30 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 20 Aug 2020 01:20:30 |

US3532063

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 09:35:30

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 (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-19T21:20:13', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '7723f06e-6935-4032-bfdb-313ed6d626e9' | System | 20 Aug 2020 01:20:30 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 20 Aug 2020 01:20:30 |

US3532063

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 09:35:30

[PC Time stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-19T21:20:27', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '7723f06e-6935-4032-bfdb-313ed6d626e9' | System | 20 Aug 2020 01:20:30 |
| User entered '19 Aug 2020 21:20'                                                                                                                                                                                                                               | System | 20 Aug 2020 01:20:30 |

US3532063

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 09:35:30**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '19 Aug 2020 12:00' | System | 18 Aug 2020 18:58:25 |

US3532063

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 09:35:30**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '20 Aug 2020 11:59' | System | 18 Aug 2020 18:58:25 |

US3532063

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 09:35:30

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 18 Aug 2020 18:58:25 |
| User entered 'Day 3' | System | 18 Aug 2020 18:58:25 |

US3532063

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 09:35:30

**HEADACHE**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-20T20:08:37', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '2e267970-b6fb-4f96-b32a-c499d1d20e9e' | System | 21 Aug 2020 00:09:12 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 21 Aug 2020 00:09:12 |

US3532063

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 09:35:30

**FATIGUE**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-20T20:08:42', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '2e267970-b6fb-4f96-b32a-c499d1d20e9e' | System | 21 Aug 2020 00:09:12 |
| User entered 'No interference with activity (1)'                                                                                                                                                                                                               | System | 21 Aug 2020 00:09:12 |



US3532063

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 09:35:30

**MUSCLE ACHES ALL OVER BODY**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-20T20:08:46', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '2e267970-b6fb-4f96-b32a-c499d1d20e9e' | System | 21 Aug 2020 00:09:12 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 21 Aug 2020 00:09:12 |

US3532063

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 09:35:30

**JOINT ACHES IN SEVERAL JOINTS**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-20T20:08:52', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '2e267970-b6fb-4f96-b32a-c499d1d20e9e' | System | 21 Aug 2020 00:09:12 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 21 Aug 2020 00:09:12 |

US3532063

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 09:35:30

**NAUSEA/VOMITING**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-20T20:08:54', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '2e267970-b6fb-4f96-b32a-c499d1d20e9e' | System | 21 Aug 2020 00:09:12 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 21 Aug 2020 00:09:12 |

US3532063

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 09:35:30

**CHILLS**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-20T20:08:57', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '2e267970-b6fb-4f96-b32a-c499d1d20e9e' | System | 21 Aug 2020 00:09:12 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 21 Aug 2020 00:09:12 |

US3532063

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 09:35:30

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 (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-20T20:09:00', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '2e267970-b6fb-4f96-b32a-c499d1d20e9e' | System | 21 Aug 2020 00:09:12 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 21 Aug 2020 00:09:12 |

US3532063

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 09:35:30

[PC Time stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-20T20:09:10', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '2e267970-b6fb-4f96-b32a-c499d1d20e9e' | System | 21 Aug 2020 00:09:12 |
| User entered '20 Aug 2020 20:09'                                                                                                                                                                                                                               | System | 21 Aug 2020 00:09:12 |

US3532063

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 09:35:30**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '20 Aug 2020 12:00' | System | 18 Aug 2020 18:58:25 |

US3532063

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 09:35:30**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '21 Aug 2020 11:59' | System | 18 Aug 2020 18:58:25 |



US3532063

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 09:35:30

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 18 Aug 2020 18:58:25 |
| User entered 'Day 4' | System | 18 Aug 2020 18:58:25 |

US3532063

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 09:35:30

**HEADACHE**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-21T22:04:32', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '8573475a-e26d-4b64-a2f0-e2e5a96f05d1' | System | 22 Aug 2020 02:05:05 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 22 Aug 2020 02:05:05 |

US3532063

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 09:35:30

**FATIGUE**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-21T22:04:39', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '8573475a-e26d-4b64-a2f0-e2e5a96f05d1' | System | 22 Aug 2020 02:05:05 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 22 Aug 2020 02:05:05 |

US3532063

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 09:35:30

**MUSCLE ACHES ALL OVER BODY**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-21T22:04:42', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '8573475a-e26d-4b64-a2f0-e2e5a96f05d1' | System | 22 Aug 2020 02:05:05 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 22 Aug 2020 02:05:05 |

US3532063

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 09:35:30

**JOINT ACHES IN SEVERAL JOINTS**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-21T22:04:46', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '8573475a-e26d-4b64-a2f0-e2e5a96f05d1' | System | 22 Aug 2020 02:05:05 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 22 Aug 2020 02:05:05 |

US3532063

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 09:35:30

**NAUSEA/VOMITING**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-21T22:04:48', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '8573475a-e26d-4b64-a2f0-e2e5a96f05d1' | System | 22 Aug 2020 02:05:05 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 22 Aug 2020 02:05:05 |

US3532063

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 09:35:30

**CHILLS**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-21T22:04:53', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '8573475a-e26d-4b64-a2f0-e2e5a96f05d1' | System | 22 Aug 2020 02:05:05 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 22 Aug 2020 02:05:05 |

US3532063

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 09:35:30

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 (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-21T22:04:57', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '8573475a-e26d-4b64-a2f0-e2e5a96f05d1' | System | 22 Aug 2020 02:05:05 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 22 Aug 2020 02:05:05 |



US3532063

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 09:35:30

[PC Time stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-21T22:05:01', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '8573475a-e26d-4b64-a2f0-e2e5a96f05d1' | System | 22 Aug 2020 02:05:05 |
| User entered '21 Aug 2020 22:05'                                                                                                                                                                                                                               | System | 22 Aug 2020 02:05:05 |

US3532063

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 09:35:30**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '21 Aug 2020 12:00' | System | 18 Aug 2020 18:58:25 |

US3532063

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 09:35:30**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '22 Aug 2020 11:59' | System | 18 Aug 2020 18:58:25 |

US3532063

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 09:35:30

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 18 Aug 2020 18:58:25 |
| User entered 'Day 5' | System | 18 Aug 2020 18:58:25 |

US3532063

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 09:35:30

**HEADACHE**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-22T21:28:52', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'bcb8460d-7d30-4600-b653-1ec7c19ce633' | System | 23 Aug 2020 01:29:14 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 23 Aug 2020 01:29:14 |

US3532063

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 09:35:30

**FATIGUE**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-22T21:28:55', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'bcb8460d-7d30-4600-b653-1ec7c19ce633' | System | 23 Aug 2020 01:29:14 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 23 Aug 2020 01:29:14 |

US3532063

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 09:35:30

**MUSCLE ACHES ALL OVER BODY**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-22T21:28:58', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'bcb8460d-7d30-4600-b653-1ec7c19ce633' | System | 23 Aug 2020 01:29:14 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 23 Aug 2020 01:29:14 |

US3532063

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 09:35:30

**JOINT ACHES IN SEVERAL JOINTS**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-22T21:29:01', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'bcb8460d-7d30-4600-b653-1ec7c19ce633' | System | 23 Aug 2020 01:29:14 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 23 Aug 2020 01:29:14 |



US3532063

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 09:35:30

**NAUSEA/VOMITING**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-22T21:29:03', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'bcb8460d-7d30-4600-b653-1ec7c19ce633' | System | 23 Aug 2020 01:29:14 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 23 Aug 2020 01:29:14 |

US3532063

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 09:35:30

**CHILLS**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-22T21:29:06', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'bcb8460d-7d30-4600-b653-1ec7c19ce633' | System | 23 Aug 2020 01:29:14 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 23 Aug 2020 01:29:14 |

US3532063

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 09:35:30

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 (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-22T21:29:09', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'bcb8460d-7d30-4600-b653-1ec7c19ce633' | System | 23 Aug 2020 01:29:14 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 23 Aug 2020 01:29:14 |

US3532063

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 09:35:30

[PC Time stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-22T21:29:12', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'bcb8460d-7d30-4600-b653-1ec7c19ce633' | System | 23 Aug 2020 01:29:14 |
| User entered '22 Aug 2020 21:29'                                                                                                                                                                                                                               | System | 23 Aug 2020 01:29:14 |

US3532063

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 09:35:30**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '22 Aug 2020 12:00' | System | 18 Aug 2020 18:58:25 |

US3532063

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 09:35:30**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '23 Aug 2020 11:59' | System | 18 Aug 2020 18:58:25 |

US3532063

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 09:35:30

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 18 Aug 2020 18:58:25 |
| User entered 'Day 6' | System | 18 Aug 2020 18:58:25 |

US3532063

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 09:35:30

**HEADACHE**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-23T21:29:04', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'b7e9aa5c-8bfa-42ab-a9a8-3ac61f17b4e2' | System | 24 Aug 2020 01:30:15 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 24 Aug 2020 01:30:15 |



US3532063

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 09:35:30

**FATIGUE**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-23T21:29:08', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'b7e9aa5c-8bfa-42ab-a9a8-3ac61f17b4e2' | System | 24 Aug 2020 01:30:15 |
| User entered 'No interference with activity (1)'                                                                                                                                                                                                               | System | 24 Aug 2020 01:30:15 |

US3532063

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 09:35:30

**MUSCLE ACHES ALL OVER BODY**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-23T21:29:11', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'b7e9aa5c-8bfa-42ab-a9a8-3ac61f17b4e2' | System | 24 Aug 2020 01:30:15 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 24 Aug 2020 01:30:15 |

US3532063

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 09:35:30

**JOINT ACHES IN SEVERAL JOINTS**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-23T21:29:13', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'b7e9aa5c-8bfa-42ab-a9a8-3ac61f17b4e2' | System | 24 Aug 2020 01:30:15 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 24 Aug 2020 01:30:15 |

US3532063

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 09:35:30

**NAUSEA/VOMITING**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-23T21:29:16', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'b7e9aa5c-8bfa-42ab-a9a8-3ac61f17b4e2' | System | 24 Aug 2020 01:30:15 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 24 Aug 2020 01:30:15 |

US3532063

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 09:35:30

**CHILLS**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-23T21:29:18', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'b7e9aa5c-8bfa-42ab-a9a8-3ac61f17b4e2' | System | 24 Aug 2020 01:30:15 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 24 Aug 2020 01:30:15 |

US3532063

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 09:35:30

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 (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-23T21:29:22', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'b7e9aa5c-8bfa-42ab-a9a8-3ac61f17b4e2' | System | 24 Aug 2020 01:30:15 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 24 Aug 2020 01:30:15 |

US3532063

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 09:35:30

[PC Time stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-23T21:29:25', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'b7e9aa5c-8bfa-42ab-a9a8-3ac61f17b4e2' | System | 24 Aug 2020 01:30:15 |
| User entered '23 Aug 2020 21:29'                                                                                                                                                                                                                               | System | 24 Aug 2020 01:30:15 |

US3532063

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 09:35:30**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '23 Aug 2020 12:00' | System | 18 Aug 2020 18:58:25 |



US3532063

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 09:35:30**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '24 Aug 2020 11:59' | System | 18 Aug 2020 18:58:25 |

US3532063

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 09:35:30

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 18 Aug 2020 18:58:25 |
| User entered 'Day 7' | System | 18 Aug 2020 18:58:25 |

US3532063

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 09:35:30

**HEADACHE**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-25T01:15:28', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'bde57e46-b4f1-432d-84a6-6d268540e75f' | System | 25 Aug 2020 05:15:52 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 25 Aug 2020 05:15:52 |

US3532063

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 09:35:30

**FATIGUE**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-25T01:15:32', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'bde57e46-b4f1-432d-84a6-6d268540e75f' | System | 25 Aug 2020 05:15:52 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 25 Aug 2020 05:15:52 |

US3532063

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 09:35:30

**MUSCLE ACHES ALL OVER BODY**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-25T01:15:35', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'bde57e46-b4f1-432d-84a6-6d268540e75f' | System | 25 Aug 2020 05:15:52 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 25 Aug 2020 05:15:52 |

US3532063

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 09:35:30

**JOINT ACHES IN SEVERAL JOINTS**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-25T01:15:37', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'bde57e46-b4f1-432d-84a6-6d268540e75f' | System | 25 Aug 2020 05:15:52 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 25 Aug 2020 05:15:52 |

US3532063

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 09:35:30

**NAUSEA/VOMITING**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-25T01:15:40', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'bde57e46-b4f1-432d-84a6-6d268540e75f' | System | 25 Aug 2020 05:15:52 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 25 Aug 2020 05:15:52 |

US3532063

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 09:35:30

**CHILLS**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-25T01:15:43', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'bde57e46-b4f1-432d-84a6-6d268540e75f' | System | 25 Aug 2020 05:15:52 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 25 Aug 2020 05:15:52 |



US3532063

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 09:35:30

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 (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-25T01:15:46', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'bde57e46-b4f1-432d-84a6-6d268540e75f' | System | 25 Aug 2020 05:15:52 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 25 Aug 2020 05:15:52 |

US3532063

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 09:35:30

[PC Time stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-25T01:15:50', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'bde57e46-b4f1-432d-84a6-6d268540e75f' | System | 25 Aug 2020 05:15:52 |
| User entered '25 Aug 2020 01:15'                                                                                                                                                                                                                               | System | 25 Aug 2020 05:15:52 |

US3532063

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 09:35:30**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '24 Aug 2020 12:00' | System | 18 Aug 2020 18:58:25 |

US3532063

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 09:35:30**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '25 Aug 2020 11:59' | System | 18 Aug 2020 18:58:25 |

US3532063

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 09:35:30**

[Was Contact Attempted?](#)

| Audit                  | User                              | Time (GMT)           |
|------------------------|-----------------------------------|----------------------|
| User entered 'Yes (Y)' | Kathy Stephens (b) (4)<br>(b) (4) | 26 Aug 2020 17:55:58 |

US3532063

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 09:35:30**

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

| Audit                      | User                              | Time (GMT)           |
|----------------------------|-----------------------------------|----------------------|
| User entered '26 Aug 2020' | Kathy Stephens (b) (4)<br>(b) (4) | 26 Aug 2020 17:55:58 |

US3532063

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 09:35:30**

[Please select one status for the follow-up contact](#)

| Audit                                      | User                              | Time (GMT)           |
|--------------------------------------------|-----------------------------------|----------------------|
| User entered 'Contact Made (CONTACT MADE)' | Kathy Stephens (b) (4)<br>(b) (4) | 26 Aug 2020 17:55:58 |

US3532063

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 09:35:30**

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit               | User                              | Time (GMT)           |
|---------------------|-----------------------------------|----------------------|
| User entered empty. | Kathy Stephens (b) (4)<br>(b) (4) | 26 Aug 2020 17:55:58 |



US3532063

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 09:35:30**

[Is the participant continuing to the next visit?](#)

| Audit                  | User                              | Time (GMT)           |
|------------------------|-----------------------------------|----------------------|
| User entered 'Yes (Y)' | Kathy Stephens (b) (4)<br>(b) (4) | 26 Aug 2020 17:56:04 |

US3532063

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 09:35:30**

[Continuing Flag](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 26 Aug 2020 17:56:04 |

US3532063

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 09:35:30**

[Was Contact Attempted?](#)

| Audit                  | User                              | Time (GMT)           |
|------------------------|-----------------------------------|----------------------|
| User entered 'Yes (Y)' | Kathy Stephens (b) (4)<br>(b) (4) | 03 Sep 2020 01:40:43 |

US3532063

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 09:35:30**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| User entered '2 Sep 2020' | Kathy Stephens (b) (4)<br>(b) (4) | 03 Sep 2020 01:40:43 |

US3532063

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 09:35:30**

[Please select one status for the follow-up contact](#)

| Audit                                      | User                              | Time (GMT)           |
|--------------------------------------------|-----------------------------------|----------------------|
| User entered 'Contact Made (CONTACT MADE)' | Kathy Stephens (b) (4)<br>(b) (4) | 03 Sep 2020 01:40:43 |

US3532063

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 09:35:30**

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit               | User                              | Time (GMT)           |
|---------------------|-----------------------------------|----------------------|
| User entered empty. | Kathy Stephens (b) (4)<br>(b) (4) | 03 Sep 2020 01:40:43 |

US3532063

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 09:35:30**

[Is the participant continuing to the next visit?](#)

| Audit                  | User                              | Time (GMT)           |
|------------------------|-----------------------------------|----------------------|
| User entered 'Yes (Y)' | Kathy Stephens (b) (4)<br>(b) (4) | 03 Sep 2020 01:40:47 |

US3532063

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 09:35:30**

[Continuing Flag](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 03 Sep 2020 01:40:47 |



US3532063

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 09:35:30**

[Was Contact Attempted?](#)

| Audit                  | User                              | Time (GMT)           |
|------------------------|-----------------------------------|----------------------|
| User entered 'Yes (Y)' | Kathy Stephens (b) (4)<br>(b) (4) | 10 Sep 2020 22:03:54 |

US3532063

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 09:35:30**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

| Audit                      | User                              | Time (GMT)           |
|----------------------------|-----------------------------------|----------------------|
| User entered '10 Sep 2020' | Kathy Stephens (b) (4)<br>(b) (4) | 10 Sep 2020 22:03:54 |

US3532063

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 09:35:30**

[Please select one status for the follow-up contact](#)

| Audit                                      | User                              | Time (GMT)           |
|--------------------------------------------|-----------------------------------|----------------------|
| User entered 'Contact Made (CONTACT MADE)' | Kathy Stephens (b) (4)<br>(b) (4) | 10 Sep 2020 22:03:54 |

US3532063

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 09:35:30**

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit               | User                              | Time (GMT)           |
|---------------------|-----------------------------------|----------------------|
| User entered empty. | Kathy Stephens (b) (4)<br>(b) (4) | 10 Sep 2020 22:03:54 |

US3532063

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 09:35:30**

[Is the participant continuing to the next visit?](#)

| Audit                  | User                              | Time (GMT)           |
|------------------------|-----------------------------------|----------------------|
| User entered 'Yes (Y)' | Kathy Stephens (b) (4)<br>(b) (4) | 10 Sep 2020 22:04:05 |

US3532063

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 09:35:30**

[Continuing Flag](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 10 Sep 2020 22:04:05 |

US3532063

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:35:30

[Was this visit performed?](#)

| Audit                  | User                              | Time (GMT)           |
|------------------------|-----------------------------------|----------------------|
| User entered 'Yes (Y)' | Kathy Stephens (b) (4)<br>(b) (4) | 16 Sep 2020 18:40:16 |

US3532063

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 26 Nov 2020 09:35:30**

[Visit date \(dd MMM yyyy\)](#)

| Audit                      | User                              | Time (GMT)           |
|----------------------------|-----------------------------------|----------------------|
| User entered '16 Sep 2020' | Kathy Stephens (b) (4)<br>(b) (4) | 16 Sep 2020 18:40:16 |



US3532063

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:35:30

[Was visit performed at the participant's home or at the clinic?](#)

| Audit                          | User                              | Time (GMT)           |
|--------------------------------|-----------------------------------|----------------------|
| User entered 'Clinic (Clinic)' | Kathy Stephens (b) (4)<br>(b) (4) | 16 Sep 2020 18:40:16 |

US3532063

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 26 Nov 2020 09:35:30**

[Folder OID](#)

| Audit                 | User   | Time (GMT)           |
|-----------------------|--------|----------------------|
| User entered 'VISIT2' | System | 16 Sep 2020 18:40:16 |

US3532063

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:35:30

[Timepoint](#)

| Audit                                            | User                              | Time (GMT)           |
|--------------------------------------------------|-----------------------------------|----------------------|
| User accepted default value 'Pre-Dose (PREDOSE)' | Kathy Stephens (b) (4)<br>(b) (4) | 16 Sep 2020 19:00:16 |

US3532063

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:35:30

[Were vital signs assessed?](#)

| Audit                  | User                              | Time (GMT)           |
|------------------------|-----------------------------------|----------------------|
| User entered 'Yes (Y)' | Kathy Stephens (b) (4)<br>(b) (4) | 16 Sep 2020 19:00:16 |

US3532063

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 09:35:30**

**Date of assessment** (*dd MMM yyyy*)

| Audit                      | User                              | Time (GMT)           |
|----------------------------|-----------------------------------|----------------------|
| User entered '16 Sep 2020' | Kathy Stephens (b) (4)<br>(b) (4) | 16 Sep 2020 19:00:16 |

US3532063

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 09:35:30**

[Time of assessment \(00:00-23:59\)](#)

| Audit                | User                              | Time (GMT)           |
|----------------------|-----------------------------------|----------------------|
| User entered '14:09' | Kathy Stephens (b) (4)<br>(b) (4) | 16 Sep 2020 19:00:16 |

US3532063

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 09:35:30**

[Vital Signs Date and Time \(derived\)](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '16 Sep 2020 14:09' | System | 16 Sep 2020 19:00:16 |

US3532063

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:35:30

Temperature (xxx.x)

| Audit                 | User                              | Time (GMT)           |
|-----------------------|-----------------------------------|----------------------|
| User entered '98.3' F | Kathy Stephens (b) (4)<br>(b) (4) | 16 Sep 2020 19:00:16 |



US3532063

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 09:35:30**

[Route of measurement](#)

| Audit                      | User                              | Time (GMT)           |
|----------------------------|-----------------------------------|----------------------|
| User entered 'Oral (Oral)' | Kathy Stephens (b) (4)<br>(b) (4) | 16 Sep 2020 19:00:16 |

US3532063

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 09:35:30**

[If Other, specify](#)

| Audit               | User                              | Time (GMT)           |
|---------------------|-----------------------------------|----------------------|
| User entered empty. | Kathy Stephens (b) (4)<br>(b) (4) | 16 Sep 2020 19:00:16 |

US3532063

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:35:30

[Pulse \(xxx\)](#)

| Audit             | User                              | Time (GMT)           |
|-------------------|-----------------------------------|----------------------|
| User entered '73' | Kathy Stephens (b) (4)<br>(b) (4) | 16 Sep 2020 19:00:16 |

US3532063

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 09:35:30**

[Pulse units](#)

| Audit              | User   | Time (GMT)           |
|--------------------|--------|----------------------|
| User entered 'bpm' | System | 16 Sep 2020 19:00:16 |

US3532063

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 09:35:30**

[Respiratory Rate \(xxx\)](#)

| Audit             | User                              | Time (GMT)           |
|-------------------|-----------------------------------|----------------------|
| User entered '16' | Kathy Stephens (b) (4)<br>(b) (4) | 16 Sep 2020 19:00:16 |

US3532063

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 09:35:30**

[Respiratory Rate units](#)

| Audit                      | User   | Time (GMT)           |
|----------------------------|--------|----------------------|
| User entered 'breaths/min' | System | 16 Sep 2020 19:00:16 |

US3532063

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 09:35:30**

[Systolic Blood Pressure \(xxx\)](#)

| Audit              | User                              | Time (GMT)           |
|--------------------|-----------------------------------|----------------------|
| User entered '105' | Kathy Stephens (b) (4)<br>(b) (4) | 16 Sep 2020 19:00:16 |

US3532063

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 09:35:30**

[Systolic Blood Pressure units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 16 Sep 2020 19:00:16 |



US3532063

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 09:35:30**

[Diastolic Blood Pressure \(xxx\)](#)

| Audit             | User                              | Time (GMT)           |
|-------------------|-----------------------------------|----------------------|
| User entered '63' | Kathy Stephens (b) (4)<br>(b) (4) | 16 Sep 2020 19:00:16 |

US3532063

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 09:35:30**

[Diastolic Blood Pressure units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 16 Sep 2020 19:00:16 |

US3532063

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:35:30

[Timepoint](#)

| Audit                                              | User                              | Time (GMT)           |
|----------------------------------------------------|-----------------------------------|----------------------|
| User accepted default value 'Post-Dose (POSTDOSE)' | Kathy Stephens (b) (4)<br>(b) (4) | 16 Sep 2020 23:37:12 |

US3532063

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:35:30

[Were vital signs assessed?](#)

| Audit                  | User                              | Time (GMT)           |
|------------------------|-----------------------------------|----------------------|
| User entered 'Yes (Y)' | Kathy Stephens (b) (4)<br>(b) (4) | 16 Sep 2020 23:37:12 |

US3532063

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 09:35:30**

**Date of assessment** (*dd MMM yyyy*)

| Audit                      | User                              | Time (GMT)           |
|----------------------------|-----------------------------------|----------------------|
| User entered '16 Sep 2020' | Kathy Stephens (b) (4)<br>(b) (4) | 16 Sep 2020 23:37:12 |

US3532063

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 09:35:30**

**Time of assessment (00:00-23:59)**

| Audit                | User                              | Time (GMT)           |
|----------------------|-----------------------------------|----------------------|
| User entered '15:43' | Kathy Stephens (b) (4)<br>(b) (4) | 16 Sep 2020 23:37:12 |

US3532063

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 09:35:30**

[Vital Signs Date and Time \(derived\)](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '16 Sep 2020 15:43' | System | 16 Sep 2020 23:37:12 |

US3532063

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:35:30

Temperature (xxx.x)

| Audit                 | User                              | Time (GMT)           |
|-----------------------|-----------------------------------|----------------------|
| User entered '97.9' F | Kathy Stephens (b) (4)<br>(b) (4) | 16 Sep 2020 23:37:12 |



US3532063

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 09:35:30**

[Route of measurement](#)

| Audit                      | User                              | Time (GMT)           |
|----------------------------|-----------------------------------|----------------------|
| User entered 'Oral (Oral)' | Kathy Stephens (b) (4)<br>(b) (4) | 16 Sep 2020 23:37:12 |

US3532063

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 09:35:30**

[If Other, specify](#)

| Audit               | User                              | Time (GMT)           |
|---------------------|-----------------------------------|----------------------|
| User entered empty. | Kathy Stephens (b) (4)<br>(b) (4) | 16 Sep 2020 23:37:12 |

US3532063

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 09:35:30**

[Pulse \(xxx\)](#)

| Audit             | User                              | Time (GMT)           |
|-------------------|-----------------------------------|----------------------|
| User entered '66' | Kathy Stephens (b) (4)<br>(b) (4) | 16 Sep 2020 23:37:12 |

US3532063

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 09:35:30**

[Pulse units](#)

| Audit              | User   | Time (GMT)           |
|--------------------|--------|----------------------|
| User entered 'bpm' | System | 16 Sep 2020 23:37:12 |

US3532063

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:35:30

[Respiratory Rate \(xxx\)](#)

| Audit             | User                              | Time (GMT)           |
|-------------------|-----------------------------------|----------------------|
| User entered '16' | Kathy Stephens (b) (4)<br>(b) (4) | 16 Sep 2020 23:37:12 |

US3532063

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 09:35:30**

[Respiratory Rate units](#)

| Audit                      | User   | Time (GMT)           |
|----------------------------|--------|----------------------|
| User entered 'breaths/min' | System | 16 Sep 2020 23:37:12 |

US3532063

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 09:35:30**

[Systolic Blood Pressure \(xxx\)](#)

| Audit              | User                              | Time (GMT)           |
|--------------------|-----------------------------------|----------------------|
| User entered '109' | Kathy Stephens (b) (4)<br>(b) (4) | 16 Sep 2020 23:37:12 |

US3532063

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 09:35:30**

[Systolic Blood Pressure units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 16 Sep 2020 23:37:12 |



US3532063

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 09:35:30**

[Diastolic Blood Pressure \(xxx\)](#)

| Audit             | User                              | Time (GMT)           |
|-------------------|-----------------------------------|----------------------|
| User entered '67' | Kathy Stephens (b) (4)<br>(b) (4) | 16 Sep 2020 23:37:12 |

US3532063

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 09:35:30**

[Diastolic Blood Pressure units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 16 Sep 2020 23:37:12 |

US3532063

**Folder: Visit 2 Day 29 (1)**

**Form: Physical Examination**

**Generated On: 26 Nov 2020 09:35:30**

[Was the physical examination performed?](#)

| Audit                  | User                              | Time (GMT)           |
|------------------------|-----------------------------------|----------------------|
| User entered 'Yes (Y)' | Kathy Stephens (b) (4)<br>(b) (4) | 16 Sep 2020 18:40:25 |

US3532063

**Folder: Visit 2 Day 29 (1)**

**Form: Physical Examination**

**Generated On: 26 Nov 2020 09:35:30**

**Date of examination (dd MMM yyyy)**

| Audit                      | User                              | Time (GMT)           |
|----------------------------|-----------------------------------|----------------------|
| User entered '16 Sep 2020' | Kathy Stephens (b) (4)<br>(b) (4) | 16 Sep 2020 18:40:25 |

US3532063

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 26 Nov 2020 09:35:30**

[Was study treatment given?](#)

| Audit                  | User                              | Time (GMT)           |
|------------------------|-----------------------------------|----------------------|
| User entered 'Yes (Y)' | Kathy Stephens (b) (4)<br>(b) (4) | 16 Sep 2020 19:20:23 |

US3532063

**Folder:** Visit 2 Day 29 (1)

**Form:** Exposure

**Generated On:** 26 Nov 2020 09:35:30

[If No, reason not given](#)

| Audit               | User                              | Time (GMT)           |
|---------------------|-----------------------------------|----------------------|
| User entered empty. | Kathy Stephens (b) (4)<br>(b) (4) | 16 Sep 2020 19:20:23 |

US3532063

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 26 Nov 2020 09:35:30**

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

| Audit               | User                              | Time (GMT)           |
|---------------------|-----------------------------------|----------------------|
| User entered empty. | Kathy Stephens (b) (4)<br>(b) (4) | 16 Sep 2020 19:20:23 |

US3532063

**Folder:** Visit 2 Day 29 (1)

**Form:** Exposure

**Generated On:** 26 Nov 2020 09:35:30

[What was the study treatment?](#)

| Audit                               | User   | Time (GMT)           |
|-------------------------------------|--------|----------------------|
| User entered 'MRNA-1273 OR PLACEBO' | System | 16 Sep 2020 19:20:23 |



US3532063

**Folder:** Visit 2 Day 29 (1)

**Form:** Exposure

**Generated On:** 26 Nov 2020 09:35:30

[What was the treatment date? \(dd MMM yyyy\)](#)

| Audit                      | User                              | Time (GMT)           |
|----------------------------|-----------------------------------|----------------------|
| User entered '16 Sep 2020' | Kathy Stephens (b) (4)<br>(b) (4) | 16 Sep 2020 19:20:23 |

US3532063

**Folder:** Visit 2 Day 29 (1)

**Form:** Exposure

**Generated On:** 26 Nov 2020 09:35:30

[What was the treatment time? \(00:00-23:59\)](#)

| Audit                | User                              | Time (GMT)           |
|----------------------|-----------------------------------|----------------------|
| User entered '15:11' | Kathy Stephens (b) (4)<br>(b) (4) | 16 Sep 2020 19:20:23 |

US3532063

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 26 Nov 2020 09:35:30**

[Treatment Date and Time \(derived\)](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '16 Sep 2020 15:11' | System | 16 Sep 2020 19:20:23 |

US3532063

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:35:30

[Which arm was used to give treatment?](#)

| Audit                              | User                              | Time (GMT)           |
|------------------------------------|-----------------------------------|----------------------|
| User entered 'Left Arm (LEFT ARM)' | Kathy Stephens (b) (4)<br>(b) (4) | 16 Sep 2020 19:20:23 |

US3532063

**Folder:** Visit 2 Day 29 (1)

**Form:** Exposure

**Generated On:** 26 Nov 2020 09:35:30

[What was the frequency of the study treatment dosing?](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'ONCE' | System | 16 Sep 2020 19:20:23 |

US3532063

**Folder:** Visit 2 Day 29 (1)

**Form:** Exposure

**Generated On:** 26 Nov 2020 09:35:30

[What was the route of administration for the study treatment?](#)

| Audit                        | User   | Time (GMT)           |
|------------------------------|--------|----------------------|
| User entered 'INTRAMUSCULAR' | System | 16 Sep 2020 19:20:23 |

US3532063

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 26 Nov 2020 09:35:30**

[Was the sample collected?](#)

| Audit                  | User                              | Time (GMT)           |
|------------------------|-----------------------------------|----------------------|
| User entered 'Yes (Y)' | Kathy Stephens (b) (4)<br>(b) (4) | 16 Sep 2020 18:58:44 |

US3532063

**Folder:** Visit 2 Day 29 (1)

**Form:** Immunogenicity Assessment

**Generated On:** 26 Nov 2020 09:35:30

**Collection date** (*dd MMM yyyy*)

| Audit                      | User                              | Time (GMT)           |
|----------------------------|-----------------------------------|----------------------|
| User entered '16 Sep 2020' | Kathy Stephens (b) (4)<br>(b) (4) | 16 Sep 2020 18:58:44 |



US3532063

**Folder:** Visit 2 Day 29 (1)

**Form:** Immunogenicity Assessment

**Generated On:** 26 Nov 2020 09:35:30

[Collection time \(00:00-23:59\)](#)

| Audit                | User                              | Time (GMT)           |
|----------------------|-----------------------------------|----------------------|
| User entered '14:50' | Kathy Stephens (b) (4)<br>(b) (4) | 16 Sep 2020 18:58:44 |

US3532063

**Folder:** Visit 2 Day 29 (1)

**Form:** Immunogenicity Assessment

**Generated On:** 26 Nov 2020 09:35:30

[Collection date and time \(derived\)](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '16 Sep 2020 14:50' | System | 16 Sep 2020 18:58:44 |

US3532063

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab**

**Generated On: 26 Nov 2020 09:35:30**

[Collection date \(dd MMM yyyy\)](#)

| Audit                      | User                              | Time (GMT)           |
|----------------------------|-----------------------------------|----------------------|
| User entered '16 Sep 2020' | Kathy Stephens (b) (4)<br>(b) (4) | 16 Sep 2020 18:59:08 |

US3532063

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:35:30

[Lab Test](#)

| Audit                                                        | User                   | Time (GMT)           |
|--------------------------------------------------------------|------------------------|----------------------|
| User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)' | Kathy Stephens (b) (4) | 16 Sep 2020 18:59:08 |

US3532063

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:35:30

[Was the sample collected?](#)

| Audit                  | User                              | Time (GMT)           |
|------------------------|-----------------------------------|----------------------|
| User entered 'Yes (Y)' | Kathy Stephens (b) (4)<br>(b) (4) | 16 Sep 2020 18:59:08 |

US3532063

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:35:30

Collection time (00:00 - 23:59)

| Audit                | User                              | Time (GMT)           |
|----------------------|-----------------------------------|----------------------|
| User entered '14:37' | Kathy Stephens (b) (4)<br>(b) (4) | 16 Sep 2020 18:59:08 |

US3532063

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 26 Nov 2020 09:35:30**

[Collection date and time \(derived\)](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '16 Sep 2020 14:37' | System | 16 Sep 2020 18:59:08 |

US3532063

**Folder:** Visit 2 Day 29 (1)

**Form:** Central Laboratory - Nasopharyngeal Swab (2)

**Generated On:** 26 Nov 2020 09:35:30

[Lab Test](#)

| Audit                                                        | User                              | Time (GMT)           |
|--------------------------------------------------------------|-----------------------------------|----------------------|
| User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)' | Kathy Stephens (b) (4)<br>(b) (4) | 16 Sep 2020 18:59:08 |



US3532063

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:35:30

[Was the sample collected?](#)

| Audit                 | User                              | Time (GMT)           |
|-----------------------|-----------------------------------|----------------------|
| User entered 'No (N)' | Kathy Stephens (b) (4)<br>(b) (4) | 16 Sep 2020 18:59:08 |

US3532063

**Folder:** Visit 2 Day 29 (1)

**Form:** Central Laboratory - Nasopharyngeal Swab (2)

**Generated On:** 26 Nov 2020 09:35:30

[Collection time \(00:00 - 23:59\)](#)

| Audit               | User                              | Time (GMT)           |
|---------------------|-----------------------------------|----------------------|
| User entered empty. | Kathy Stephens (b) (4)<br>(b) (4) | 16 Sep 2020 18:59:08 |

US3532063

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 26 Nov 2020 09:35:30**

[Collection date and time \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 16 Sep 2020 18:59:08 |

US3532063

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 09:35:30**

[Is the participant continuing to the next visit?](#)

| Audit                  | User                              | Time (GMT)           |
|------------------------|-----------------------------------|----------------------|
| User entered 'Yes (Y)' | Kathy Stephens (b) (4)<br>(b) (4) | 16 Sep 2020 23:37:20 |

US3532063

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 09:35:30**

[Continuing Flag](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 16 Sep 2020 23:37:20 |

US3532063

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 26 Nov 2020 09:35:30

**TIMEPOINT**

| Audit                                                                | User   | Time (GMT)           |
|----------------------------------------------------------------------|--------|----------------------|
| Data entry locked.                                                   | System | 16 Sep 2020 19:20:23 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 16 Sep 2020 19:20:23 |

US3532063

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 26 Nov 2020 09:35:30

Was **TEMPERATURE** taken?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-16T15:43:30', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '78ade3f6-a2ff-46b1-8297-328c79be2bed' | System | 16 Sep 2020 19:43:58 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                                         | System | 16 Sep 2020 19:43:58 |

US3532063

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 26 Nov 2020 09:35:30

Please record your **TEMPERATURE** in °F

| Audit                                                                                                                                                                                                                                                                              | User   | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-16T15:43:42', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '78ade3f6-a2ff-46b1-8297-328c79be2bed' User entered '97.9' | System | 16 Sep 2020 19:43:58 |



US3532063

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 26 Nov 2020 09:35:30

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

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-16T15:43:46', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '78ade3f6-a2ff-46b1-8297-328c79be2bed' | System | 16 Sep 2020 19:43:58 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 16 Sep 2020 19:43:58 |

US3532063

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 26 Nov 2020 09:35:30**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-16T15:43:55', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '78ade3f6-a2ff-46b1-8297-328c79be2bed' | System | 16 Sep 2020 19:43:58 |
| User entered '16 Sep 2020 15:43'                                                                                                                                                                                                                               | System | 16 Sep 2020 19:43:58 |

US3532063

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 26 Nov 2020 09:35:30**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '16 Sep 2020 15:31' | System | 16 Sep 2020 19:20:23 |

US3532063

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 26 Nov 2020 09:35:30**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '16 Sep 2020 18:01' | System | 16 Sep 2020 19:20:23 |

US3532063

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 26 Nov 2020 09:35:30

**TIMEPOINT**

| Audit                                             | User   | Time (GMT)           |
|---------------------------------------------------|--------|----------------------|
| Data entry locked.                                | System | 16 Sep 2020 19:20:23 |
| User entered 'Day 1, after vaccination (at home)' | System | 16 Sep 2020 19:20:23 |

US3532063

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 26 Nov 2020 09:35:30

Was **TEMPERATURE** taken?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-16T21:21:12', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'cc16f35a-cbb6-4f34-8cd4-26efdf1d3484' | System | 17 Sep 2020 01:22:57 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                                         | System | 17 Sep 2020 01:22:57 |

US3532063

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 26 Nov 2020 09:35:30

Please record your **TEMPERATURE** in °F

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-16T21:21:22', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'cc16f35a-cbb6-4f34-8cd4-26efdf1d3484' | System | 17 Sep 2020 01:22:57 |
| User entered '97.5'                                                                                                                                                                                                                                            | System | 17 Sep 2020 01:22:57 |

US3532063

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 26 Nov 2020 09:35:30

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

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-16T21:21:25', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'cc16f35a-cbb6-4f34-8cd4-26efdf1d3484' | System | 17 Sep 2020 01:22:57 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 17 Sep 2020 01:22:57 |



US3532063

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 26 Nov 2020 09:35:30

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-16T21:21:31', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'cc16f35a-cbb6-4f34-8cd4-26efdf1d3484' | System | 17 Sep 2020 01:22:57 |
| User entered '16 Sep 2020 21:21'                                                                                                                                                                                                                               | System | 17 Sep 2020 01:22:57 |

US3532063

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 26 Nov 2020 09:35:30**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '16 Sep 2020 18:56' | System | 16 Sep 2020 19:20:23 |

US3532063

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 26 Nov 2020 09:35:30**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '17 Sep 2020 11:59' | System | 16 Sep 2020 19:20:23 |

US3532063

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 09:35:30

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 16 Sep 2020 19:20:23 |
| User entered 'Day 2' | System | 16 Sep 2020 19:20:23 |

US3532063

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 09:35:30

Was **TEMPERATURE** taken?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-17T21:49:39', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'b42452d4-f21c-4c1f-9821-0eb7bbf95df0' | System | 18 Sep 2020 01:49:58 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                                         | System | 18 Sep 2020 01:49:58 |

US3532063

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 09:35:30

Please record your **TEMPERATURE** in °F

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-17T21:49:46', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'b42452d4-f21c-4c1f-9821-0eb7bbf95df0' | System | 18 Sep 2020 01:49:58 |
| User entered '96.5'                                                                                                                                                                                                                                            | System | 18 Sep 2020 01:49:58 |

US3532063

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 09:35:30

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

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-17T21:49:50', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'b42452d4-f21c-4c1f-9821-0eb7bbf95df0' | System | 18 Sep 2020 01:49:58 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 18 Sep 2020 01:49:58 |

US3532063

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 26 Nov 2020 09:35:30**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-17T21:49:53', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'b42452d4-f21c-4c1f-9821-0eb7bbf95df0' | System | 18 Sep 2020 01:49:58 |
| User entered '17 Sep 2020 21:49'                                                                                                                                                                                                                               | System | 18 Sep 2020 01:49:58 |



US3532063

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 26 Nov 2020 09:35:30**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '17 Sep 2020 12:00' | System | 16 Sep 2020 19:20:23 |

US3532063

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 26 Nov 2020 09:35:30**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '18 Sep 2020 11:59' | System | 16 Sep 2020 19:20:23 |

US3532063

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 26 Nov 2020 09:35:30

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 16 Sep 2020 19:20:23 |
| User entered 'Day 3' | System | 16 Sep 2020 19:20:23 |

US3532063

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 26 Nov 2020 09:35:30

Was **TEMPERATURE** taken?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-19T04:43:19', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'efbb6ef5-7bf5-41c6-9d80-ec760d1b514d' | System | 19 Sep 2020 08:43:36 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                                         | System | 19 Sep 2020 08:43:36 |

US3532063

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 26 Nov 2020 09:35:30

Please record your **TEMPERATURE** in °F

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-19T04:43:26', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'efbb6ef5-7bf5-41c6-9d80-ec760d1b514d' | System | 19 Sep 2020 08:43:36 |
| User entered '96.5'                                                                                                                                                                                                                                            | System | 19 Sep 2020 08:43:36 |

US3532063

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 26 Nov 2020 09:35:30

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

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-19T04:43:30', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'efbb6ef5-7bf5-41c6-9d80-ec760d1b514d' | System | 19 Sep 2020 08:43:36 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 19 Sep 2020 08:43:36 |

US3532063

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 26 Nov 2020 09:35:30

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-19T04:43:34', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'efbb6ef5-7bf5-41c6-9d80-ec760d1b514d' | System | 19 Sep 2020 08:43:36 |
| User entered '19 Sep 2020 04:43'                                                                                                                                                                                                                               | System | 19 Sep 2020 08:43:36 |

US3532063

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 26 Nov 2020 09:35:30**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '18 Sep 2020 12:00' | System | 16 Sep 2020 19:20:23 |



US3532063

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 26 Nov 2020 09:35:30**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '19 Sep 2020 11:59' | System | 16 Sep 2020 19:20:23 |

US3532063

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 09:35:30

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 16 Sep 2020 19:20:23 |
| User entered 'Day 4' | System | 16 Sep 2020 19:20:23 |

US3532063

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 09:35:30

Was **TEMPERATURE** taken?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-19T20:59:31', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '816adde5-117f-45cf-b886-96d0a8c3e5c7' | System | 20 Sep 2020 00:59:45 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                                         | System | 20 Sep 2020 00:59:45 |

US3532063

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 09:35:30

Please record your **TEMPERATURE** in °F

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-19T20:59:37', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '816adde5-117f-45cf-b886-96d0a8c3e5c7' | System | 20 Sep 2020 00:59:45 |
| User entered '95.4'                                                                                                                                                                                                                                            | System | 20 Sep 2020 00:59:45 |

US3532063

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 09:35:30

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

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-19T20:59:40', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '816adde5-117f-45cf-b886-96d0a8c3e5c7' | System | 20 Sep 2020 00:59:45 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 20 Sep 2020 00:59:45 |

US3532063

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 26 Nov 2020 09:35:30**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-19T20:59:44', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '816adde5-117f-45cf-b886-96d0a8c3e5c7' | System | 20 Sep 2020 00:59:45 |
| User entered '19 Sep 2020 20:59'                                                                                                                                                                                                                               | System | 20 Sep 2020 00:59:45 |

US3532063

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 26 Nov 2020 09:35:30**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '19 Sep 2020 12:00' | System | 16 Sep 2020 19:20:23 |

US3532063

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 26 Nov 2020 09:35:30**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '20 Sep 2020 11:59' | System | 16 Sep 2020 19:20:23 |



US3532063

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 26 Nov 2020 09:35:30

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 16 Sep 2020 19:20:23 |
| User entered 'Day 5' | System | 16 Sep 2020 19:20:23 |

US3532063

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 26 Nov 2020 09:35:30

Was **TEMPERATURE** taken?

| Audit                                                                                                                                                                                                                                                                                 | User   | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-20T21:06:31', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '801b6404-4437-4d0b-aaee-655ed53328bb' User entered 'Yes (Y)' | System | 21 Sep 2020 01:06:48 |

US3532063

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 26 Nov 2020 09:35:30

Please record your **TEMPERATURE** in °F

| Audit                                                                                                                                                                                                                                                                              | User   | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-20T21:06:36', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '801b6404-4437-4d0b-aace-655ed53328bb' User entered '96.4' | System | 21 Sep 2020 01:06:48 |

US3532063

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 26 Nov 2020 09:35:30

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

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-20T21:06:39', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '801b6404-4437-4d0b-aace-655ed53328bb' | System | 21 Sep 2020 01:06:48 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 21 Sep 2020 01:06:48 |

US3532063

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 26 Nov 2020 09:35:30

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                                                           | User   | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-20T21:06:45', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '801b6404-4437-4d0b-aaee-655ed53328bb' User entered '20 Sep 2020 21:06' | System | 21 Sep 2020 01:06:48 |
|                                                                                                                                                                                                                                                                                                 | System | 21 Sep 2020 01:06:48 |

US3532063

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 26 Nov 2020 09:35:30**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '20 Sep 2020 12:00' | System | 16 Sep 2020 19:20:23 |

US3532063

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 26 Nov 2020 09:35:30**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '21 Sep 2020 11:59' | System | 16 Sep 2020 19:20:23 |

US3532063

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 26 Nov 2020 09:35:30

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 16 Sep 2020 19:20:23 |
| User entered 'Day 6' | System | 16 Sep 2020 19:20:23 |



US3532063

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 26 Nov 2020 09:35:30

Was **TEMPERATURE** taken?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-21T21:20:09', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '24626056-0746-4047-8bce-e8aaf591674b' | System | 22 Sep 2020 01:21:02 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                                         | System | 22 Sep 2020 01:21:02 |

US3532063

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 26 Nov 2020 09:35:30

Please record your **TEMPERATURE** in °F

| Audit                                                                                                                                                                                                                                                                              | User   | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-21T21:20:52', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '24626056-0746-4047-8bce-e8aaf591674b' User entered '97.1' | System | 22 Sep 2020 01:21:02 |
|                                                                                                                                                                                                                                                                                    | System | 22 Sep 2020 01:21:02 |

US3532063

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 26 Nov 2020 09:35:30

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

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-21T21:20:55', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '24626056-0746-4047-8bce-e8aaf591674b' | System | 22 Sep 2020 01:21:02 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 22 Sep 2020 01:21:02 |

US3532063

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 26 Nov 2020 09:35:30

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-21T21:20:59', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '24626056-0746-4047-8bce-e8aaf591674b' | System | 22 Sep 2020 01:21:02 |
| User entered '21 Sep 2020 21:20'                                                                                                                                                                                                                               | System | 22 Sep 2020 01:21:02 |

US3532063

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 26 Nov 2020 09:35:30**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '21 Sep 2020 12:00' | System | 16 Sep 2020 19:20:23 |

US3532063

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 26 Nov 2020 09:35:30**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '22 Sep 2020 11:59' | System | 16 Sep 2020 19:20:23 |

US3532063

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 26 Nov 2020 09:35:30

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 16 Sep 2020 19:20:23 |
| User entered 'Day 7' | System | 16 Sep 2020 19:20:23 |

US3532063

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 26 Nov 2020 09:35:30

Was **TEMPERATURE** taken?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-22T21:01:09', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '07db9866-378f-4506-aa7c-2cf3f0c69dc6' | System | 23 Sep 2020 01:02:36 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                                         | System | 23 Sep 2020 01:02:36 |



US3532063

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 26 Nov 2020 09:35:30

Please record your **TEMPERATURE** in °F

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-22T21:02:26', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '07db9866-378f-4506-aa7c-2cf3f0c69dc6' | System | 23 Sep 2020 01:02:36 |
| User entered '97.1'                                                                                                                                                                                                                                            | System | 23 Sep 2020 01:02:36 |

US3532063

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 26 Nov 2020 09:35:30

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

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-22T21:02:29', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '07db9866-378f-4506-aa7c-2cf3f0c69dc6' | System | 23 Sep 2020 01:02:36 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 23 Sep 2020 01:02:36 |

US3532063

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 26 Nov 2020 09:35:30**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-22T21:02:32', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '07db9866-378f-4506-aa7c-2cf3f0c69dc6' | System | 23 Sep 2020 01:02:36 |
| User entered '22 Sep 2020 21:02'                                                                                                                                                                                                                               | System | 23 Sep 2020 01:02:36 |

US3532063

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 26 Nov 2020 09:35:30**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '22 Sep 2020 12:00' | System | 16 Sep 2020 19:20:23 |

US3532063

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 26 Nov 2020 09:35:30**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '23 Sep 2020 11:59' | System | 16 Sep 2020 19:20:23 |

US3532063

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 09:35:30

**TIMEPOINT**

| Audit                                                                | User   | Time (GMT)           |
|----------------------------------------------------------------------|--------|----------------------|
| Data entry locked.                                                   | System | 16 Sep 2020 19:20:23 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 16 Sep 2020 19:20:23 |

US3532063

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 09:35:30

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 (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-16T15:44:11', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'cfd28096-adf7-46b7-bac6-415654e56509' | System | 16 Sep 2020 19:44:42 |
| User entered 'None (1)'                                                                                                                                                                                                                                        | System | 16 Sep 2020 19:44:42 |

US3532063

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 09:35:30

Is there any REDNESS AT INJECTION SITE?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-16T15:44:23', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'cfd28096-adf7-46b7-bac6-415654e56509' | System | 16 Sep 2020 19:44:42 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 16 Sep 2020 19:44:42 |



US3532063

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 09:35:30

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

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-16T15:44:29', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'cfd28096-adf7-46b7-bac6-415654e56509' | System | 16 Sep 2020 19:44:42 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 16 Sep 2020 19:44:42 |

US3532063

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 09:35:30

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 (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-16T15:44:36', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'cfd28096-adf7-46b7-bac6-415654e56509' | System | 16 Sep 2020 19:44:42 |
| User entered 'None (1)'                                                                                                                                                                                                                                        | System | 16 Sep 2020 19:44:42 |

US3532063

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 09:35:30**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-16T15:44:39', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'cfd28096-adf7-46b7-bac6-415654e56509' | System | 16 Sep 2020 19:44:42 |
| User entered '16 Sep 2020 15:44'                                                                                                                                                                                                                               | System | 16 Sep 2020 19:44:42 |

US3532063

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 09:35:30**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '16 Sep 2020 15:31' | System | 16 Sep 2020 19:20:23 |

US3532063

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 09:35:30**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '16 Sep 2020 18:01' | System | 16 Sep 2020 19:20:23 |

US3532063

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 26 Nov 2020 09:35:30

**TIMEPOINT**

| Audit                                             | User   | Time (GMT)           |
|---------------------------------------------------|--------|----------------------|
| Data entry locked.                                | System | 16 Sep 2020 19:20:23 |
| User entered 'Day 1, after vaccination (at home)' | System | 16 Sep 2020 19:20:23 |

US3532063

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 09:35:30**

[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 (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-16T21:21:43', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'c1a7339d-b0b2-44c8-a054-eb01a5fb00be' | System | 17 Sep 2020 01:23:47 |
| User entered 'None (1)'                                                                                                                                                                                                                                        | System | 17 Sep 2020 01:23:47 |

US3532063

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 26 Nov 2020 09:35:30

Is there any REDNESS AT INJECTION SITE?

| Audit                                                                                                                                                                                                                                                                                | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-16T21:22:20', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'c1a7339d-b0b2-44c8-a054-eb01a5fb00be' User entered 'No (N)' | System | 17 Sep 2020 01:23:47 |



US3532063

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 26 Nov 2020 09:35:30

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

| Audit                                                                                                                                                                                                                                                                                | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-16T21:22:30', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'c1a7339d-b0b2-44c8-a054-eb01a5fb00be' User entered 'No (N)' | System | 17 Sep 2020 01:23:47 |

US3532063

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 26 Nov 2020 09:35:30

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 (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-16T21:22:37', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'c1a7339d-b0b2-44c8-a054-eb01a5fb00be' | System | 17 Sep 2020 01:23:47 |
| User entered 'None (1)'                                                                                                                                                                                                                                        | System | 17 Sep 2020 01:23:47 |

US3532063

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 09:35:30**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                                                           | User   | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-16T21:22:40', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'c1a7339d-b0b2-44c8-a054-eb01a5fb00be' User entered '16 Sep 2020 21:22' | System | 17 Sep 2020 01:23:47 |

US3532063

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 09:35:30**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '16 Sep 2020 18:56' | System | 16 Sep 2020 19:20:23 |

US3532063

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 09:35:30**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '17 Sep 2020 11:59' | System | 16 Sep 2020 19:20:23 |

US3532063

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 26 Nov 2020 09:35:30

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 16 Sep 2020 19:20:23 |
| User entered 'Day 2' | System | 16 Sep 2020 19:20:23 |

US3532063

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 26 Nov 2020 09:35:30

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 (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-17T21:50:47', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '03a4a3b2-a293-4d0c-9255-b2262e862c75' | System | 18 Sep 2020 01:52:15 |
| User entered 'None (1)'                                                                                                                                                                                                                                        | System | 18 Sep 2020 01:52:15 |

US3532063

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 26 Nov 2020 09:35:30

Is there any REDNESS AT INJECTION SITE?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-17T21:51:01', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '03a4a3b2-a293-4d0c-9255-b2262e862c75' | System | 18 Sep 2020 01:52:15 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 18 Sep 2020 01:52:15 |



US3532063

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 26 Nov 2020 09:35:30

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

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-17T21:51:41', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '03a4a3b2-a293-4d0c-9255-b2262e862c75' | System | 18 Sep 2020 01:52:15 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 18 Sep 2020 01:52:15 |

US3532063

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 26 Nov 2020 09:35:30

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 (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-17T21:51:50', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '03a4a3b2-a293-4d0c-9255-b2262e862c75' | System | 18 Sep 2020 01:52:15 |
| User entered 'None (1)'                                                                                                                                                                                                                                        | System | 18 Sep 2020 01:52:15 |

US3532063

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 09:35:30**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-17T21:51:55', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '03a4a3b2-a293-4d0c-9255-b2262e862c75' | System | 18 Sep 2020 01:52:15 |
| User entered '17 Sep 2020 21:51'                                                                                                                                                                                                                               | System | 18 Sep 2020 01:52:15 |

US3532063

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 09:35:30**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '17 Sep 2020 12:00' | System | 16 Sep 2020 19:20:23 |

US3532063

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 09:35:30**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '18 Sep 2020 11:59' | System | 16 Sep 2020 19:20:23 |

US3532063

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 26 Nov 2020 09:35:30

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 16 Sep 2020 19:20:23 |
| User entered 'Day 3' | System | 16 Sep 2020 19:20:23 |

US3532063

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 26 Nov 2020 09:35:30

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 (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-19T04:43:42', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '1f776142-da5c-4ede-b3fa-7c2700e7100e' | System | 19 Sep 2020 08:44:04 |
| User entered 'None (1)'                                                                                                                                                                                                                                        | System | 19 Sep 2020 08:44:04 |

US3532063

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 26 Nov 2020 09:35:30

Is there any REDNESS AT INJECTION SITE?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-19T04:43:47', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '1f776142-da5c-4ede-b3fa-7c2700e7100e' | System | 19 Sep 2020 08:44:04 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 19 Sep 2020 08:44:04 |



US3532063

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 26 Nov 2020 09:35:30

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

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-19T04:43:50', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '1f776142-da5c-4ede-b3fa-7c2700e7100e' | System | 19 Sep 2020 08:44:04 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 19 Sep 2020 08:44:04 |

US3532063

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 26 Nov 2020 09:35:30

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 (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-19T04:43:58', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '1f776142-da5c-4ede-b3fa-7c2700e7100e' | System | 19 Sep 2020 08:44:04 |
| User entered 'None (1)'                                                                                                                                                                                                                                        | System | 19 Sep 2020 08:44:04 |

US3532063

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 09:35:30**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-19T04:44:01', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '1f776142-da5c-4ede-b3fa-7c2700e7100e' | System | 19 Sep 2020 08:44:04 |
| User entered '19 Sep 2020 04:44'                                                                                                                                                                                                                               | System | 19 Sep 2020 08:44:04 |

US3532063

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 09:35:30**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '18 Sep 2020 12:00' | System | 16 Sep 2020 19:20:23 |

US3532063

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 09:35:30**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '19 Sep 2020 11:59' | System | 16 Sep 2020 19:20:23 |

US3532063

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 26 Nov 2020 09:35:30

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 16 Sep 2020 19:20:23 |
| User entered 'Day 4' | System | 16 Sep 2020 19:20:23 |

US3532063

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 26 Nov 2020 09:35:30

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 (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-19T21:00:05', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '81a2866d-b72d-4a40-864a-5bea5f5c64ce' | System | 20 Sep 2020 01:02:29 |
| User entered 'None (1)'                                                                                                                                                                                                                                        | System | 20 Sep 2020 01:02:29 |

US3532063

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 26 Nov 2020 09:35:30

Is there any REDNESS AT INJECTION SITE?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-19T21:00:08', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '81a2866d-b72d-4a40-864a-5bea5f5c64ce' | System | 20 Sep 2020 01:02:29 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 20 Sep 2020 01:02:29 |



US3532063

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 26 Nov 2020 09:35:30

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

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-19T21:00:25', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '81a2866d-b72d-4a40-864a-5bea5f5c64ce' | System | 20 Sep 2020 01:02:29 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                                         | System | 20 Sep 2020 01:02:29 |

US3532063

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 26 Nov 2020 09:35:30

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

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

| Audit                                                                                                                                                                                                                                                                             | User   | Time (GMT)           |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-19T21:02:15', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '81a2866d-b72d-4a40-864a-5bea5f5c64ce' User entered '300' | System | 20 Sep 2020 01:02:29 |
|                                                                                                                                                                                                                                                                                   | System | 20 Sep 2020 01:02:29 |

US3532063

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 26 Nov 2020 09:35:30

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 (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-19T21:02:22', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '81a2866d-b72d-4a40-864a-5bea5f5c64ce' | System | 20 Sep 2020 01:02:29 |
| User entered 'None (1)'                                                                                                                                                                                                                                        | System | 20 Sep 2020 01:02:29 |

US3532063

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 09:35:30**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-19T21:02:27', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '81a2866d-b72d-4a40-864a-5bea5f5c64ce' | System | 20 Sep 2020 01:02:29 |
| User entered '19 Sep 2020 21:02'                                                                                                                                                                                                                               | System | 20 Sep 2020 01:02:29 |

US3532063

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 09:35:30**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '19 Sep 2020 12:00' | System | 16 Sep 2020 19:20:23 |

US3532063

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 09:35:30**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '20 Sep 2020 11:59' | System | 16 Sep 2020 19:20:23 |

US3532063

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 26 Nov 2020 09:35:30

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 16 Sep 2020 19:20:23 |
| User entered 'Day 5' | System | 16 Sep 2020 19:20:23 |

US3532063

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 26 Nov 2020 09:35:30

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 (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-20T21:07:43', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'c92b38ef-5139-4b96-b6b6-aaf0c87807f5' | System | 21 Sep 2020 01:08:12 |
| User entered 'None (1)'                                                                                                                                                                                                                                        | System | 21 Sep 2020 01:08:12 |



US3532063

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 26 Nov 2020 09:35:30

Is there any REDNESS AT INJECTION SITE?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-20T21:07:57', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'c92b38ef-5139-4b96-b6b6-aaf0c87807f5' | System | 21 Sep 2020 01:08:12 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 21 Sep 2020 01:08:12 |

US3532063

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 26 Nov 2020 09:35:30

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

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-20T21:08:01', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'c92b38ef-5139-4b96-b6b6-aaf0c87807f5' | System | 21 Sep 2020 01:08:12 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 21 Sep 2020 01:08:12 |

US3532063

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 26 Nov 2020 09:35:30

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 (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-20T21:08:06', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'c92b38ef-5139-4b96-b6b6-aaf0c87807f5' | System | 21 Sep 2020 01:08:12 |
| User entered 'None (1)'                                                                                                                                                                                                                                        | System | 21 Sep 2020 01:08:12 |

US3532063

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 09:35:30**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-20T21:08:11', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'c92b38ef-5139-4b96-b6b6-aaf0c87807f5' | System | 21 Sep 2020 01:08:12 |
| User entered '20 Sep 2020 21:08'                                                                                                                                                                                                                               | System | 21 Sep 2020 01:08:12 |

US3532063

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 09:35:30**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '20 Sep 2020 12:00' | System | 16 Sep 2020 19:20:23 |

US3532063

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 09:35:30**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '21 Sep 2020 11:59' | System | 16 Sep 2020 19:20:23 |

US3532063

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 26 Nov 2020 09:35:30

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 16 Sep 2020 19:20:23 |
| User entered 'Day 6' | System | 16 Sep 2020 19:20:23 |

US3532063

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 26 Nov 2020 09:35:30

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 (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-21T21:22:09', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '929d747c-1524-491f-9015-caab30337c75' | System | 22 Sep 2020 01:22:30 |
| User entered 'None (1)'                                                                                                                                                                                                                                        | System | 22 Sep 2020 01:22:30 |



US3532063

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 26 Nov 2020 09:35:30

Is there any REDNESS AT INJECTION SITE?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-21T21:22:13', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '929d747c-1524-491f-9015-caab30337c75' | System | 22 Sep 2020 01:22:30 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 22 Sep 2020 01:22:30 |

US3532063

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 26 Nov 2020 09:35:30

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

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-21T21:22:15', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '929d747c-1524-491f-9015-caab30337c75' | System | 22 Sep 2020 01:22:30 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 22 Sep 2020 01:22:30 |

US3532063

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 26 Nov 2020 09:35:30

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 (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-21T21:22:22', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '929d747c-1524-491f-9015-caab30337c75' | System | 22 Sep 2020 01:22:30 |
| User entered 'None (1)'                                                                                                                                                                                                                                        | System | 22 Sep 2020 01:22:30 |

US3532063

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 09:35:30**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-21T21:22:25', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '929d747c-1524-491f-9015-caab30337c75' | System | 22 Sep 2020 01:22:30 |
| User entered '21 Sep 2020 21:22'                                                                                                                                                                                                                               | System | 22 Sep 2020 01:22:30 |

US3532063

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 09:35:30**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '21 Sep 2020 12:00' | System | 16 Sep 2020 19:20:23 |

US3532063

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 09:35:30**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '22 Sep 2020 11:59' | System | 16 Sep 2020 19:20:23 |

US3532063

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 26 Nov 2020 09:35:30

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 16 Sep 2020 19:20:23 |
| User entered 'Day 7' | System | 16 Sep 2020 19:20:23 |

US3532063

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 26 Nov 2020 09:35:30

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 (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-22T21:02:36', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'a8290410-03f4-42ff-a898-f5df41a09949' | System | 23 Sep 2020 01:02:55 |
| User entered 'None (1)'                                                                                                                                                                                                                                        | System | 23 Sep 2020 01:02:55 |



US3532063

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 26 Nov 2020 09:35:30

Is there any REDNESS AT INJECTION SITE?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-22T21:02:40', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'a8290410-03f4-42ff-a898-f5df41a09949' | System | 23 Sep 2020 01:02:55 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 23 Sep 2020 01:02:55 |

US3532063

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 26 Nov 2020 09:35:30

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

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-22T21:02:42', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'a8290410-03f4-42ff-a898-f5df41a09949' | System | 23 Sep 2020 01:02:55 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 23 Sep 2020 01:02:55 |

US3532063

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 26 Nov 2020 09:35:30

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 (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-22T21:02:49', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'a8290410-03f4-42ff-a898-f5df41a09949' | System | 23 Sep 2020 01:02:55 |
| User entered 'None (1)'                                                                                                                                                                                                                                        | System | 23 Sep 2020 01:02:55 |

US3532063

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 09:35:30**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-22T21:02:53', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'a8290410-03f4-42ff-a898-f5df41a09949' | System | 23 Sep 2020 01:02:55 |
| User entered '22 Sep 2020 21:02'                                                                                                                                                                                                                               | System | 23 Sep 2020 01:02:55 |

US3532063

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 09:35:30**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '22 Sep 2020 12:00' | System | 16 Sep 2020 19:20:23 |

US3532063

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 09:35:30**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '23 Sep 2020 11:59' | System | 16 Sep 2020 19:20:23 |

US3532063

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 09:35:30

**TIMEPOINT**

| Audit                                                                | User   | Time (GMT)           |
|----------------------------------------------------------------------|--------|----------------------|
| Data entry locked.                                                   | System | 16 Sep 2020 19:20:23 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 16 Sep 2020 19:20:23 |

US3532063

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 09:35:30

**HEADACHE**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-16T15:44:45', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '2e380d05-0ba1-46bb-830d-d798035b48e6' | System | 16 Sep 2020 19:45:16 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 16 Sep 2020 19:45:16 |



US3532063

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 09:35:30

**FATIGUE**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-16T15:44:52', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '2e380d05-0ba1-46bb-830d-d798035b48e6' | System | 16 Sep 2020 19:45:16 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 16 Sep 2020 19:45:16 |

US3532063

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 09:35:30

**MUSCLE ACHES ALL OVER BODY**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-16T15:44:55', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '2e380d05-0ba1-46bb-830d-d798035b48e6' | System | 16 Sep 2020 19:45:16 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 16 Sep 2020 19:45:16 |

US3532063

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 09:35:30

**JOINT ACHES IN SEVERAL JOINTS**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-16T15:45:00', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '2e380d05-0ba1-46bb-830d-d798035b48e6' | System | 16 Sep 2020 19:45:16 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 16 Sep 2020 19:45:16 |

US3532063

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 09:35:30

**NAUSEA/VOMITING**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-16T15:45:05', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '2e380d05-0ba1-46bb-830d-d798035b48e6' | System | 16 Sep 2020 19:45:16 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 16 Sep 2020 19:45:16 |

US3532063

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 09:35:30

**CHILLS**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-16T15:45:08', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '2e380d05-0ba1-46bb-830d-d798035b48e6' | System | 16 Sep 2020 19:45:16 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 16 Sep 2020 19:45:16 |

US3532063

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 09:35:30

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 (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-16T15:45:11', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '2e380d05-0ba1-46bb-830d-d798035b48e6' | System | 16 Sep 2020 19:45:16 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 16 Sep 2020 19:45:16 |

US3532063

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 09:35:30

[PC Time stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-16T15:45:14', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '2e380d05-0ba1-46bb-830d-d798035b48e6' | System | 16 Sep 2020 19:45:16 |
| User entered '16 Sep 2020 15:45'                                                                                                                                                                                                                               | System | 16 Sep 2020 19:45:16 |

US3532063

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 09:35:30**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '16 Sep 2020 15:31' | System | 16 Sep 2020 19:20:23 |



US3532063

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 09:35:30**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '16 Sep 2020 18:01' | System | 16 Sep 2020 19:20:23 |

US3532063

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 09:35:30

**TIMEPOINT**

| Audit                                             | User   | Time (GMT)           |
|---------------------------------------------------|--------|----------------------|
| Data entry locked.                                | System | 16 Sep 2020 19:20:23 |
| User entered 'Day 1, after vaccination (at home)' | System | 16 Sep 2020 19:20:23 |

US3532063

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 09:35:30

**HEADACHE**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-16T21:22:45', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'b870c7b3-be62-441c-8d66-48a77d0c6860' | System | 17 Sep 2020 01:23:57 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 17 Sep 2020 01:23:57 |

US3532063

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 09:35:30

**FATIGUE**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-16T21:22:48', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'b870c7b3-be62-441c-8d66-48a77d0c6860' | System | 17 Sep 2020 01:23:57 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 17 Sep 2020 01:23:57 |

US3532063

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 09:35:30

**MUSCLE ACHES ALL OVER BODY**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-16T21:22:51', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'b870c7b3-be62-441c-8d66-48a77d0c6860' | System | 17 Sep 2020 01:23:57 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 17 Sep 2020 01:23:57 |

US3532063

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 09:35:30

**JOINT ACHES IN SEVERAL JOINTS**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-16T21:22:54', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'b870c7b3-be62-441c-8d66-48a77d0c6860' | System | 17 Sep 2020 01:23:57 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 17 Sep 2020 01:23:57 |

US3532063

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 09:35:30

**NAUSEA/VOMITING**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-16T21:22:57', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'b870c7b3-be62-441c-8d66-48a77d0c6860' | System | 17 Sep 2020 01:23:57 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 17 Sep 2020 01:23:57 |

US3532063

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 09:35:30

CHILLS

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-16T21:23:00', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'b870c7b3-be62-441c-8d66-48a77d0c6860' | System | 17 Sep 2020 01:23:57 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 17 Sep 2020 01:23:57 |



US3532063

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 09:35:30

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 (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-16T21:23:04', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'b870c7b3-be62-441c-8d66-48a77d0c6860' | System | 17 Sep 2020 01:23:57 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 17 Sep 2020 01:23:57 |

US3532063

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 09:35:30

[PC Time stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-16T21:23:11', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'b870c7b3-be62-441c-8d66-48a77d0c6860' | System | 17 Sep 2020 01:23:57 |
| User entered '16 Sep 2020 21:23'                                                                                                                                                                                                                               | System | 17 Sep 2020 01:23:57 |

US3532063

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 09:35:30**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '16 Sep 2020 18:56' | System | 16 Sep 2020 19:20:23 |

US3532063

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 09:35:30**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '17 Sep 2020 11:59' | System | 16 Sep 2020 19:20:23 |

US3532063

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 09:35:30

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 16 Sep 2020 19:20:23 |
| User entered 'Day 2' | System | 16 Sep 2020 19:20:23 |

US3532063

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 09:35:30

**HEADACHE**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-17T21:52:00', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '6945ac54-1c96-437a-bd1e-c436c21309dc' | System | 18 Sep 2020 01:52:32 |
| User entered 'No interference with activity (1)'                                                                                                                                                                                                               | System | 18 Sep 2020 01:52:32 |

US3532063

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 09:35:30

**FATIGUE**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-17T21:52:07', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '6945ac54-1c96-437a-bd1e-c436c21309dc' | System | 18 Sep 2020 01:52:32 |
| User entered 'No interference with activity (1)'                                                                                                                                                                                                               | System | 18 Sep 2020 01:52:32 |

US3532063

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 09:35:30

**MUSCLE ACHES ALL OVER BODY**

| Audit                                                                                                                                                                                                                                                                                  | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-17T21:52:10', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '6945ac54-1c96-437a-bd1e-c436c21309dc' User entered 'None (0)' | System | 18 Sep 2020 01:52:32 |
|                                                                                                                                                                                                                                                                                        | System | 18 Sep 2020 01:52:32 |



US3532063

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 09:35:30

**JOINT ACHES IN SEVERAL JOINTS**

| Audit                                                                                                                                                                                                                                                                                  | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-17T21:52:12', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '6945ac54-1c96-437a-bd1e-c436c21309dc' User entered 'None (0)' | System | 18 Sep 2020 01:52:32 |
|                                                                                                                                                                                                                                                                                        | System | 18 Sep 2020 01:52:32 |

US3532063

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 09:35:30

**NAUSEA/VOMITING**

| Audit                                                                                                                                                                                                                                                                                  | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-17T21:52:15', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '6945ac54-1c96-437a-bd1e-c436c21309dc' User entered 'None (0)' | System | 18 Sep 2020 01:52:32 |
|                                                                                                                                                                                                                                                                                        | System | 18 Sep 2020 01:52:32 |

US3532063

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 09:35:30

**CHILLS**

| Audit                                                                                                                                                                                                                                                                                  | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-17T21:52:19', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '6945ac54-1c96-437a-bd1e-c436c21309dc' User entered 'None (0)' | System | 18 Sep 2020 01:52:32 |
|                                                                                                                                                                                                                                                                                        | System | 18 Sep 2020 01:52:32 |

US3532063

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 09:35:30

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 (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-17T21:52:22', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '6945ac54-1c96-437a-bd1e-c436c21309dc' User entered 'No (N)' | System | 18 Sep 2020 01:52:32 |

US3532063

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 09:35:30

[PC Time stamp](#)

| Audit                                                                                                                                                                                                                                                                                           | User   | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-17T21:52:28', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '6945ac54-1c96-437a-bd1e-c436c21309dc' User entered '17 Sep 2020 21:52' | System | 18 Sep 2020 01:52:32 |
|                                                                                                                                                                                                                                                                                                 | System | 18 Sep 2020 01:52:32 |

US3532063

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 09:35:30**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '17 Sep 2020 12:00' | System | 16 Sep 2020 19:20:23 |

US3532063

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 09:35:30**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '18 Sep 2020 11:59' | System | 16 Sep 2020 19:20:23 |

US3532063

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 09:35:30

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 16 Sep 2020 19:20:23 |
| User entered 'Day 3' | System | 16 Sep 2020 19:20:23 |



US3532063

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 09:35:30

**HEADACHE**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-19T04:44:06', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'e20019b9-ceb6-47e1-9407-fa8a0cf56f3d' | System | 19 Sep 2020 08:44:32 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 19 Sep 2020 08:44:32 |

US3532063

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 09:35:30

**FATIGUE**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-19T04:44:11', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'e20019b9-ceb6-47e1-9407-fa8a0cf56f3d' | System | 19 Sep 2020 08:44:32 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 19 Sep 2020 08:44:32 |

US3532063

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 09:35:30

**MUSCLE ACHES ALL OVER BODY**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-19T04:44:14', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'e20019b9-ceb6-47e1-9407-fa8a0cf56f3d' | System | 19 Sep 2020 08:44:32 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 19 Sep 2020 08:44:32 |

US3532063

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 09:35:30

**JOINT ACHES IN SEVERAL JOINTS**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-19T04:44:16', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'e20019b9-ceb6-47e1-9407-fa8a0cf56f3d' | System | 19 Sep 2020 08:44:32 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 19 Sep 2020 08:44:32 |

US3532063

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 09:35:30

**NAUSEA/VOMITING**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-19T04:44:19', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'e20019b9-ceb6-47e1-9407-fa8a0cf56f3d' | System | 19 Sep 2020 08:44:32 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 19 Sep 2020 08:44:32 |

US3532063

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 09:35:30

**CHILLS**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-19T04:44:21', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'e20019b9-ceb6-47e1-9407-fa8a0cf56f3d' | System | 19 Sep 2020 08:44:32 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 19 Sep 2020 08:44:32 |

US3532063

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 09:35:30

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 (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-19T04:44:25', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'e20019b9-ceb6-47e1-9407-fa8a0cf56f3d' | System | 19 Sep 2020 08:44:32 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 19 Sep 2020 08:44:32 |

US3532063

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 09:35:30

[PC Time stamp](#)

| Audit                                                                                                                                                                                                                                                                                           | User   | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-19T04:44:30', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'e20019b9-ceb6-47e1-9407-fa8a0cf56f3d' User entered '19 Sep 2020 04:44' | System | 19 Sep 2020 08:44:32 |
|                                                                                                                                                                                                                                                                                                 | System | 19 Sep 2020 08:44:32 |



US3532063

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 09:35:30**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '18 Sep 2020 12:00' | System | 16 Sep 2020 19:20:23 |

US3532063

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 09:35:30**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '19 Sep 2020 11:59' | System | 16 Sep 2020 19:20:23 |

US3532063

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 09:35:30

[TIMEPOINT](#)

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 16 Sep 2020 19:20:23 |
| User entered 'Day 4' | System | 16 Sep 2020 19:20:23 |

US3532063

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 09:35:30

**HEADACHE**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-19T21:02:31', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'baa9ff98-3eac-45f4-b48f-596b0f25a265' | System | 20 Sep 2020 01:02:54 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 20 Sep 2020 01:02:54 |

US3532063

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 09:35:30

**FATIGUE**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-19T21:02:33', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'baa9ff98-3eac-45f4-b48f-596b0f25a265' | System | 20 Sep 2020 01:02:54 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 20 Sep 2020 01:02:54 |

US3532063

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 09:35:30

**MUSCLE ACHES ALL OVER BODY**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-19T21:02:36', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'baa9ff98-3eac-45f4-b48f-596b0f25a265' | System | 20 Sep 2020 01:02:54 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 20 Sep 2020 01:02:54 |

US3532063

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 09:35:30

**JOINT ACHES IN SEVERAL JOINTS**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-19T21:02:39', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'baa9ff98-3eac-45f4-b48f-596b0f25a265' | System | 20 Sep 2020 01:02:54 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 20 Sep 2020 01:02:54 |

US3532063

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 09:35:30

**NAUSEA/VOMITING**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-19T21:02:41', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'baa9ff98-3eac-45f4-b48f-596b0f25a265' | System | 20 Sep 2020 01:02:54 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 20 Sep 2020 01:02:54 |



US3532063

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 09:35:30

**CHILLS**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-19T21:02:43', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'baa9ff98-3eac-45f4-b48f-596b0f25a265' | System | 20 Sep 2020 01:02:54 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 20 Sep 2020 01:02:54 |

US3532063

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 09:35:30

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 (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-19T21:02:47', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'baa9ff98-3eac-45f4-b48f-596b0f25a265' | System | 20 Sep 2020 01:02:54 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 20 Sep 2020 01:02:54 |

US3532063

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 09:35:30**

[PC Time stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-19T21:02:51', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'baa9ff98-3eac-45f4-b48f-596b0f25a265' | System | 20 Sep 2020 01:02:54 |
| User entered '19 Sep 2020 21:02'                                                                                                                                                                                                                               | System | 20 Sep 2020 01:02:54 |

US3532063

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 09:35:30**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '19 Sep 2020 12:00' | System | 16 Sep 2020 19:20:23 |

US3532063

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 09:35:30**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '20 Sep 2020 11:59' | System | 16 Sep 2020 19:20:23 |

US3532063

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 09:35:30

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 16 Sep 2020 19:20:23 |
| User entered 'Day 5' | System | 16 Sep 2020 19:20:23 |

US3532063

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 09:35:30

**HEADACHE**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-20T21:08:15', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'ee003044-3da1-4211-814c-7d99ad4b3df5' | System | 21 Sep 2020 01:08:39 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 21 Sep 2020 01:08:39 |

US3532063

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 09:35:30

**FATIGUE**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-20T21:08:18', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'ee003044-3da1-4211-814c-7d99ad4b3df5' | System | 21 Sep 2020 01:08:39 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 21 Sep 2020 01:08:39 |



US3532063

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 09:35:30

**MUSCLE ACHES ALL OVER BODY**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-20T21:08:21', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'ee003044-3da1-4211-814c-7d99ad4b3df5' | System | 21 Sep 2020 01:08:39 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 21 Sep 2020 01:08:39 |

US3532063

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 09:35:30

**JOINT ACHES IN SEVERAL JOINTS**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-20T21:08:23', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'ee003044-3da1-4211-814c-7d99ad4b3df5' | System | 21 Sep 2020 01:08:39 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 21 Sep 2020 01:08:39 |

US3532063

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 09:35:30

**NAUSEA/VOMITING**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-20T21:08:26', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'ee003044-3da1-4211-814c-7d99ad4b3df5' | System | 21 Sep 2020 01:08:39 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 21 Sep 2020 01:08:39 |

US3532063

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 09:35:30

**CHILLS**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-20T21:08:29', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'ee003044-3da1-4211-814c-7d99ad4b3df5' | System | 21 Sep 2020 01:08:39 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 21 Sep 2020 01:08:39 |

US3532063

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 09:35:30

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 (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-20T21:08:32', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'ee003044-3da1-4211-814c-7d99ad4b3df5' | System | 21 Sep 2020 01:08:39 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 21 Sep 2020 01:08:39 |

US3532063

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 09:35:30

[PC Time stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-20T21:08:35', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'ee003044-3da1-4211-814c-7d99ad4b3df5' | System | 21 Sep 2020 01:08:39 |
| User entered '20 Sep 2020 21:08'                                                                                                                                                                                                                               | System | 21 Sep 2020 01:08:39 |

US3532063

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 09:35:30**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '20 Sep 2020 12:00' | System | 16 Sep 2020 19:20:23 |

US3532063

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 09:35:30**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '21 Sep 2020 11:59' | System | 16 Sep 2020 19:20:23 |



US3532063

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 09:35:30

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 16 Sep 2020 19:20:23 |
| User entered 'Day 6' | System | 16 Sep 2020 19:20:23 |

US3532063

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 09:35:30

**HEADACHE**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-21T21:22:29', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '961afd1e-60a3-4d45-90f0-f070a89bf241' | System | 22 Sep 2020 01:22:50 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 22 Sep 2020 01:22:50 |

US3532063

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 09:35:30

**FATIGUE**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-21T21:22:31', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '961afd1e-60a3-4d45-90f0-f070a89bf241' | System | 22 Sep 2020 01:22:50 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 22 Sep 2020 01:22:50 |

US3532063

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 09:35:30

**MUSCLE ACHES ALL OVER BODY**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-21T21:22:33', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '961afd1e-60a3-4d45-90f0-f070a89bf241' | System | 22 Sep 2020 01:22:50 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 22 Sep 2020 01:22:50 |

US3532063

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 09:35:30

**JOINT ACHES IN SEVERAL JOINTS**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-21T21:22:35', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '961afd1e-60a3-4d45-90f0-f070a89bf241' | System | 22 Sep 2020 01:22:50 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 22 Sep 2020 01:22:50 |

US3532063

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 09:35:30

**NAUSEA/VOMITING**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-21T21:22:38', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '961afd1e-60a3-4d45-90f0-f070a89bf241' | System | 22 Sep 2020 01:22:50 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 22 Sep 2020 01:22:50 |

US3532063

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 09:35:30

CHILLS

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-21T21:22:40', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '961afd1e-60a3-4d45-90f0-f070a89bf241' | System | 22 Sep 2020 01:22:50 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 22 Sep 2020 01:22:50 |

US3532063

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 09:35:30

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 (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-21T21:22:44', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '961afd1e-60a3-4d45-90f0-f070a89bf241' | System | 22 Sep 2020 01:22:50 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 22 Sep 2020 01:22:50 |



US3532063

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 09:35:30

[PC Time stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-21T21:22:49', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '961afd1e-60a3-4d45-90f0-f070a89bf241' | System | 22 Sep 2020 01:22:50 |
| User entered '21 Sep 2020 21:22'                                                                                                                                                                                                                               | System | 22 Sep 2020 01:22:50 |

US3532063

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 09:35:30**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '21 Sep 2020 12:00' | System | 16 Sep 2020 19:20:23 |

US3532063

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 09:35:30**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '22 Sep 2020 11:59' | System | 16 Sep 2020 19:20:23 |

US3532063

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 09:35:30

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 16 Sep 2020 19:20:23 |
| User entered 'Day 7' | System | 16 Sep 2020 19:20:23 |

US3532063

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 09:35:30

**HEADACHE**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-22T21:02:57', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'e237a03d-e2a7-4b45-9155-71865cf6ff66' | System | 23 Sep 2020 01:03:22 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 23 Sep 2020 01:03:22 |

US3532063

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 09:35:30

**FATIGUE**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-22T21:03:00', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'e237a03d-e2a7-4b45-9155-71865cf6ff66' | System | 23 Sep 2020 01:03:22 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 23 Sep 2020 01:03:22 |

US3532063

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 09:35:30

**MUSCLE ACHES ALL OVER BODY**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-22T21:03:02', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'e237a03d-e2a7-4b45-9155-71865cf6ff66' | System | 23 Sep 2020 01:03:22 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 23 Sep 2020 01:03:22 |

US3532063

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 09:35:30

**JOINT ACHES IN SEVERAL JOINTS**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-22T21:03:09', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'e237a03d-e2a7-4b45-9155-71865cf6ff66' | System | 23 Sep 2020 01:03:22 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 23 Sep 2020 01:03:22 |



US3532063

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 09:35:30

**NAUSEA/VOMITING**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-22T21:03:11', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'e237a03d-e2a7-4b45-9155-71865cf6ff66' | System | 23 Sep 2020 01:03:22 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 23 Sep 2020 01:03:22 |

US3532063

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 09:35:30

**CHILLS**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-22T21:03:14', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'e237a03d-e2a7-4b45-9155-71865cf6ff66' | System | 23 Sep 2020 01:03:22 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 23 Sep 2020 01:03:22 |

US3532063

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 09:35:30

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 (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-22T21:03:16', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'e237a03d-e2a7-4b45-9155-71865cf6ff66' | System | 23 Sep 2020 01:03:22 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 23 Sep 2020 01:03:22 |

US3532063

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 09:35:30

[PC Time stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-22T21:03:19', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'e237a03d-e2a7-4b45-9155-71865cf6ff66' | System | 23 Sep 2020 01:03:22 |
| User entered '22 Sep 2020 21:03'                                                                                                                                                                                                                               | System | 23 Sep 2020 01:03:22 |

US3532063

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 09:35:30**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '22 Sep 2020 12:00' | System | 16 Sep 2020 19:20:23 |

US3532063

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 09:35:30**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '23 Sep 2020 11:59' | System | 16 Sep 2020 19:20:23 |

US3532063

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 09:35:30**

[Was Contact Attempted?](#)

| Audit                  | User                              | Time (GMT)           |
|------------------------|-----------------------------------|----------------------|
| User entered 'Yes (Y)' | Kathy Stephens (b) (4)<br>(b) (4) | 26 Sep 2020 20:31:05 |

US3532063

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 09:35:30**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

| Audit                      | User                              | Time (GMT)           |
|----------------------------|-----------------------------------|----------------------|
| User entered '26 Sep 2020' | Kathy Stephens (b) (4)<br>(b) (4) | 26 Sep 2020 20:31:05 |



US3532063

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 09:35:30**

[Please select one status for the follow-up contact](#)

| Audit                                      | User                              | Time (GMT)           |
|--------------------------------------------|-----------------------------------|----------------------|
| User entered 'Contact Made (CONTACT MADE)' | Kathy Stephens (b) (4)<br>(b) (4) | 26 Sep 2020 20:31:05 |

US3532063

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 09:35:30**

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit               | User                              | Time (GMT)           |
|---------------------|-----------------------------------|----------------------|
| User entered empty. | Kathy Stephens (b) (4)<br>(b) (4) | 26 Sep 2020 20:31:05 |

US3532063

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 09:35:30**

[Is the participant continuing to the next visit?](#)

| Audit                  | User                              | Time (GMT)           |
|------------------------|-----------------------------------|----------------------|
| User entered 'Yes (Y)' | Kathy Stephens (b) (4)<br>(b) (4) | 26 Sep 2020 20:31:11 |

US3532063

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 09:35:30**

[Continuing Flag](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 26 Sep 2020 20:31:11 |

US3532063

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 09:35:30**

[Was Contact Attempted?](#)

| Audit                  | User                              | Time (GMT)           |
|------------------------|-----------------------------------|----------------------|
| User entered 'Yes (Y)' | Kathy Stephens (b) (4)<br>(b) (4) | 03 Oct 2020 21:25:30 |

US3532063

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 09:35:30**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| User entered '3 Oct 2020' | Kathy Stephens (b) (4)<br>(b) (4) | 03 Oct 2020 21:25:30 |

US3532063

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 09:35:30**

[Please select one status for the follow-up contact](#)

| Audit                                      | User                              | Time (GMT)           |
|--------------------------------------------|-----------------------------------|----------------------|
| User entered 'Contact Made (CONTACT MADE)' | Kathy Stephens (b) (4)<br>(b) (4) | 03 Oct 2020 21:25:30 |

US3532063

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 09:35:30**

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit               | User                              | Time (GMT)           |
|---------------------|-----------------------------------|----------------------|
| User entered empty. | Kathy Stephens (b) (4)<br>(b) (4) | 03 Oct 2020 21:25:30 |



US3532063

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 09:35:30**

[Is the participant continuing to the next visit?](#)

| Audit                  | User                              | Time (GMT)           |
|------------------------|-----------------------------------|----------------------|
| User entered 'Yes (Y)' | Kathy Stephens (b) (4)<br>(b) (4) | 03 Oct 2020 21:25:36 |

US3532063

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 09:35:30**

[Continuing Flag](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 03 Oct 2020 21:25:36 |

US3532063

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 09:35:30**

[Was Contact Attempted?](#)

| Audit                  | User                              | Time (GMT)           |
|------------------------|-----------------------------------|----------------------|
| User entered 'Yes (Y)' | Kathy Stephens (b) (4)<br>(b) (4) | 14 Oct 2020 17:43:38 |

US3532063

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 09:35:30**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

| Audit                      | User                              | Time (GMT)           |
|----------------------------|-----------------------------------|----------------------|
| User entered '10 Oct 2020' | Kathy Stephens (b) (4)<br>(b) (4) | 14 Oct 2020 17:43:38 |

US3532063

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 09:35:30**

[Please select one status for the follow-up contact](#)

| Audit                                      | User                              | Time (GMT)           |
|--------------------------------------------|-----------------------------------|----------------------|
| User entered 'Contact Made (CONTACT MADE)' | Kathy Stephens (b) (4)<br>(b) (4) | 14 Oct 2020 17:43:38 |

US3532063

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 09:35:30**

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit               | User                              | Time (GMT)           |
|---------------------|-----------------------------------|----------------------|
| User entered empty. | Kathy Stephens (b) (4)<br>(b) (4) | 14 Oct 2020 17:43:38 |

US3532063

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 09:35:30**

[Is the participant continuing to the next visit?](#)

| Audit                  | User                              | Time (GMT)           |
|------------------------|-----------------------------------|----------------------|
| User entered 'Yes (Y)' | Kathy Stephens (b) (4)<br>(b) (4) | 14 Oct 2020 17:43:44 |

US3532063

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 09:35:30**

[Continuing Flag](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 14 Oct 2020 17:43:44 |



US3532063

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:35:30

[Was this visit performed?](#)

| Audit                  | User                              | Time (GMT)           |
|------------------------|-----------------------------------|----------------------|
| User entered 'Yes (Y)' | Kathy Stephens (b) (4)<br>(b) (4) | 14 Oct 2020 18:02:11 |

US3532063

**Folder:** Visit 3 Day 57 (1)

**Form:** Visit Date

**Generated On:** 26 Nov 2020 09:35:30

[Visit date \(dd MMM yyyy\)](#)

| Audit                      | User                              | Time (GMT)           |
|----------------------------|-----------------------------------|----------------------|
| User entered '14 Oct 2020' | Kathy Stephens (b) (4)<br>(b) (4) | 14 Oct 2020 18:02:11 |

US3532063

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:35:30

[Was visit performed at the participant's home or at the clinic?](#)

| Audit                          | User                              | Time (GMT)           |
|--------------------------------|-----------------------------------|----------------------|
| User entered 'Clinic (Clinic)' | Kathy Stephens (b) (4)<br>(b) (4) | 14 Oct 2020 18:02:11 |

US3532063

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 26 Nov 2020 09:35:30**

[Folder OID](#)

| Audit                 | User   | Time (GMT)           |
|-----------------------|--------|----------------------|
| User entered 'VISIT3' | System | 14 Oct 2020 18:02:11 |

US3532063

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:35:30

[Were vital signs assessed?](#)

| Audit                  | User                              | Time (GMT)           |
|------------------------|-----------------------------------|----------------------|
| User entered 'Yes (Y)' | Kathy Stephens (b) (4)<br>(b) (4) | 14 Oct 2020 18:03:11 |

US3532063

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:35:30

Date of assessment (*dd MMM yyyy*)

| Audit                      | User                              | Time (GMT)           |
|----------------------------|-----------------------------------|----------------------|
| User entered '14 Oct 2020' | Kathy Stephens (b) (4)<br>(b) (4) | 14 Oct 2020 18:03:11 |

US3532063

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 09:35:30**

[Time of assessment \(00:00-23:59\)](#)

| Audit                | User                              | Time (GMT)           |
|----------------------|-----------------------------------|----------------------|
| User entered '13:36' | Kathy Stephens (b) (4)<br>(b) (4) | 14 Oct 2020 18:03:11 |

US3532063

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 09:35:30**

[Vital Signs Date and Time \(derived\)](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '14 Oct 2020 13:36' | System | 14 Oct 2020 18:03:11 |



US3532063

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:35:30

Temperature (xxx.x)

| Audit                 | User                              | Time (GMT)           |
|-----------------------|-----------------------------------|----------------------|
| User entered '97.9' F | Kathy Stephens (b) (4)<br>(b) (4) | 14 Oct 2020 18:03:11 |

US3532063

**Folder:** Visit 3 Day 57 (1)

**Form:** Vital Signs

**Generated On:** 26 Nov 2020 09:35:30

[Route of measurement](#)

| Audit                      | User                              | Time (GMT)           |
|----------------------------|-----------------------------------|----------------------|
| User entered 'Oral (Oral)' | Kathy Stephens (b) (4)<br>(b) (4) | 14 Oct 2020 18:03:11 |

US3532063

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:35:30

[If Other, specify](#)

| Audit               | User                              | Time (GMT)           |
|---------------------|-----------------------------------|----------------------|
| User entered empty. | Kathy Stephens (b) (4)<br>(b) (4) | 14 Oct 2020 18:03:11 |

US3532063

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:35:30

[Pulse \(xxx\)](#)

| Audit             | User                              | Time (GMT)           |
|-------------------|-----------------------------------|----------------------|
| User entered '65' | Kathy Stephens (b) (4)<br>(b) (4) | 14 Oct 2020 18:03:11 |

US3532063

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 09:35:30**

[Pulse units](#)

| Audit              | User   | Time (GMT)           |
|--------------------|--------|----------------------|
| User entered 'bpm' | System | 14 Oct 2020 18:03:11 |

US3532063

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:35:30

[Respiratory Rate \(xxx\)](#)

| Audit             | User                              | Time (GMT)           |
|-------------------|-----------------------------------|----------------------|
| User entered '14' | Kathy Stephens (b) (4)<br>(b) (4) | 14 Oct 2020 18:03:11 |

US3532063

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 09:35:30**

[Respiratory Rate units](#)

| Audit                      | User   | Time (GMT)           |
|----------------------------|--------|----------------------|
| User entered 'breaths/min' | System | 14 Oct 2020 18:03:11 |

US3532063

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:35:30

Systolic Blood Pressure (xxx)

| Audit              | User                              | Time (GMT)           |
|--------------------|-----------------------------------|----------------------|
| User entered '113' | Kathy Stephens (b) (4)<br>(b) (4) | 14 Oct 2020 18:03:11 |



US3532063

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 09:35:30**

[Systolic Blood Pressure units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 14 Oct 2020 18:03:11 |

US3532063

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 09:35:30**

[Diastolic Blood Pressure \(xxx\)](#)

| Audit             | User                              | Time (GMT)           |
|-------------------|-----------------------------------|----------------------|
| User entered '74' | Kathy Stephens (b) (4)<br>(b) (4) | 14 Oct 2020 18:03:11 |

US3532063

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 09:35:30**

[Diastolic Blood Pressure units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 14 Oct 2020 18:03:11 |

US3532063

**Folder: Visit 3 Day 57 (1)**

**Form: Physical Examination**

**Generated On: 26 Nov 2020 09:35:30**

[Was the physical examination performed?](#)

| Audit                 | User                              | Time (GMT)           |
|-----------------------|-----------------------------------|----------------------|
| User entered 'No (N)' | Kathy Stephens (b) (4)<br>(b) (4) | 14 Oct 2020 18:03:16 |

US3532063

**Folder: Visit 3 Day 57 (1)**

**Form: Physical Examination**

**Generated On: 26 Nov 2020 09:35:30**

**Date of examination (dd MMM yyyy)**

| Audit               | User                              | Time (GMT)           |
|---------------------|-----------------------------------|----------------------|
| User entered empty. | Kathy Stephens (b) (4)<br>(b) (4) | 14 Oct 2020 18:03:16 |

US3532063

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 26 Nov 2020 09:35:30**

[Was the sample collected?](#)

| Audit                  | User                              | Time (GMT)           |
|------------------------|-----------------------------------|----------------------|
| User entered 'Yes (Y)' | Kathy Stephens (b) (4)<br>(b) (4) | 14 Oct 2020 18:03:45 |

US3532063

**Folder:** Visit 3 Day 57 (1)

**Form:** Immunogenicity Assessment

**Generated On:** 26 Nov 2020 09:35:30

[Collection date \(dd MMM yyyy\)](#)

| Audit                      | User                              | Time (GMT)           |
|----------------------------|-----------------------------------|----------------------|
| User entered '14 Oct 2020' | Kathy Stephens (b) (4)<br>(b) (4) | 14 Oct 2020 18:03:45 |

US3532063

**Folder:** Visit 3 Day 57 (1)

**Form:** Immunogenicity Assessment

**Generated On:** 26 Nov 2020 09:35:30

[Collection time \(00:00-23:59\)](#)

| Audit                | User                              | Time (GMT)           |
|----------------------|-----------------------------------|----------------------|
| User entered '13:54' | Kathy Stephens (b) (4)<br>(b) (4) | 14 Oct 2020 18:03:45 |



US3532063

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 26 Nov 2020 09:35:30**

[Collection date and time \(derived\)](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '14 Oct 2020 13:54' | System | 14 Oct 2020 18:03:45 |

US3532063

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 09:35:30**

[Is the participant continuing to the next visit?](#)

| Audit                  | User                              | Time (GMT)           |
|------------------------|-----------------------------------|----------------------|
| User entered 'Yes (Y)' | Kathy Stephens (b) (4)<br>(b) (4) | 14 Oct 2020 18:03:49 |

US3532063

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 09:35:30**

[Continuing Flag](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 14 Oct 2020 18:03:49 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

**TIMEPOINT**

| Audit                 | User   | Time (GMT)           |
|-----------------------|--------|----------------------|
| Data entry locked.    | System | 18 Aug 2020 18:58:25 |
| User entered 'Day 64' | System | 18 Aug 2020 18:58:25 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[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 (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-10-18T12:03:53', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'e1968fb9-8231-4dcd-97c6-2a1c499b7ab9' User entered 'No (N)' | System | 18 Oct 2020 16:04:18 |
|                                                                                                                                                                                                                                                                                      | System | 18 Oct 2020 16:04:18 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

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 (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-10-18T12:03:58', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'e1968fb9-8231-4dcd-97c6-2a1c499b7ab9' User entered 'No (N)' | System | 18 Oct 2020 16:04:18 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Date and time of submission](#)

| Audit                                                                                                                                                                                                                                                                                              | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-10-18T12:04:16', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'e1968fb9-8231-4dcd-97c6-2a1c499b7ab9' User entered '18 Oct 2020 12:04:16' | System | 18 Oct 2020 16:04:18 |
|                                                                                                                                                                                                                                                                                                    | System | 18 Oct 2020 16:04:18 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| Data entry locked.               | System | 18 Aug 2020 18:58:25 |
| User entered '18 Oct 2020 00:01' | System | 18 Aug 2020 18:58:25 |



US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| Data entry locked.               | System | 18 Aug 2020 18:58:25 |
| User entered '22 Oct 2020 23:59' | System | 18 Aug 2020 18:58:25 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

**TIMEPOINT**

| Audit                 | User   | Time (GMT)           |
|-----------------------|--------|----------------------|
| Data entry locked.    | System | 18 Aug 2020 18:58:25 |
| User entered 'Day 71' | System | 18 Aug 2020 18:58:25 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[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 (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-10-25T07:39:43', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '7c544880-5d79-4f1d-8173-a40465d757b9' | System | 25 Oct 2020 11:40:03 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 25 Oct 2020 11:40:03 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

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 (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-10-25T07:39:51', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '7c544880-5d79-4f1d-8173-a40465d757b9' | System | 25 Oct 2020 11:40:03 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 25 Oct 2020 11:40:03 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Date and time of submission](#)

| Audit                                                                                                                                                                                                                                                                                              | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-10-25T07:39:59', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '7c544880-5d79-4f1d-8173-a40465d757b9' User entered '25 Oct 2020 07:39:59' | System | 25 Oct 2020 11:40:03 |
|                                                                                                                                                                                                                                                                                                    | System | 25 Oct 2020 11:40:03 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| Data entry locked.               | System | 18 Aug 2020 18:58:25 |
| User entered '25 Oct 2020 00:01' | System | 18 Aug 2020 18:58:25 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| Data entry locked.               | System | 18 Aug 2020 18:58:25 |
| User entered '29 Oct 2020 23:59' | System | 18 Aug 2020 18:58:25 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

**TIMEPOINT**

| Audit                 | User   | Time (GMT)           |
|-----------------------|--------|----------------------|
| Data entry locked.    | System | 18 Aug 2020 18:58:25 |
| User entered 'Day 78' | System | 18 Aug 2020 18:58:25 |



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

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 (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-11-02T18:09:40', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'cf34177f-e585-4aa8-bf15-43151f6c03cd' User entered 'Yes (Y)' | System | 03 Nov 2020 00:10:32 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

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 (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-11-02T18:09:46', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'cf34177f-e585-4aa8-bf15-43151f6c03cd' | System | 03 Nov 2020 00:10:32 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 03 Nov 2020 00:10:32 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

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 (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-11-02T18:09:51', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'cf34177f-e585-4aa8-bf15-43151f6c03cd' | System | 03 Nov 2020 00:10:32 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 03 Nov 2020 00:10:32 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[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 (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-11-02T18:10:01', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'cf34177f-e585-4aa8-bf15-43151f6c03cd' User entered 'Yes (Y)' | System | 03 Nov 2020 00:10:32 |

**US3532063**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Please 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 (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-11-02T18:10:11', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'cf34177f-e585-4aa8-bf15-43151f6c03cd' | System | 03 Nov 2020 00:10:32 |
| User entered 'I confirm I have read this message and will call the study clinic immediately (9)'                                                                                                                                                               | System | 03 Nov 2020 00:10:32 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Date and time of submission](#)

| Audit                                                                                                                                                                                                                                                                                              | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-11-02T18:10:23', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'cf34177f-e585-4aa8-bf15-43151f6c03cd' User entered '02 Nov 2020 18:10:23' | System | 03 Nov 2020 00:10:32 |
|                                                                                                                                                                                                                                                                                                    | System | 03 Nov 2020 00:10:32 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| Data entry locked.               | System | 18 Aug 2020 18:58:25 |
| User entered '01 Nov 2020 00:01' | System | 18 Aug 2020 18:58:25 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| Data entry locked.               | System | 18 Aug 2020 18:58:25 |
| User entered '05 Nov 2020 23:59' | System | 18 Aug 2020 18:58:25 |



US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

**TIMEPOINT**

| Audit                 | User   | Time (GMT)           |
|-----------------------|--------|----------------------|
| Data entry locked.    | System | 18 Aug 2020 18:58:25 |
| User entered 'Day 92' | System | 18 Aug 2020 18:58:25 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

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 (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-11-15T07:23:13', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'ab81e6c5-7928-4cf7-a167-8b73a126f6f3' | System | 15 Nov 2020 13:23:39 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 15 Nov 2020 13:23:39 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

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 (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-11-15T07:23:10', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'ab81e6c5-7928-4cf7-a167-8b73a126f6f3' | System | 15 Nov 2020 13:23:39 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 15 Nov 2020 13:23:39 |

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Date and time of submission](#)

| Audit                                                                                                                                                                                                                                                                                              | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-11-15T07:23:35', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'ab81e6c5-7928-4cf7-a167-8b73a126f6f3' User entered '15 Nov 2020 07:23:35' | System | 15 Nov 2020 13:23:39 |
|                                                                                                                                                                                                                                                                                                    | System | 15 Nov 2020 13:23:39 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| Data entry locked.               | System | 18 Aug 2020 18:58:25 |
| User entered '15 Nov 2020 00:01' | System | 18 Aug 2020 18:58:25 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| Data entry locked.               | System | 18 Aug 2020 18:58:25 |
| User entered '19 Nov 2020 23:59' | System | 18 Aug 2020 18:58:25 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

**TIMEPOINT**

| Audit                                    | User   | Time (GMT)           |
|------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.    | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered 'Day 61' | System | 19 Nov 2020 22:22:31 |

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '15 Oct 2020 00:01' | System | 19 Nov 2020 22:22:31 |



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '19 Oct 2020 23:59' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

**TIMEPOINT**

| Audit                                    | User   | Time (GMT)           |
|------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.    | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered 'Day 68' | System | 19 Nov 2020 22:22:31 |

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '22 Oct 2020 00:01' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '26 Oct 2020 23:59' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

**TIMEPOINT**

| Audit                                    | User   | Time (GMT)           |
|------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.    | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered 'Day 75' | System | 19 Nov 2020 22:22:31 |

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '29 Oct 2020 00:01' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '02 Nov 2020 23:59' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

**TIMEPOINT**

| Audit                                    | User   | Time (GMT)           |
|------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.    | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered 'Day 82' | System | 19 Nov 2020 22:22:31 |



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '05 Nov 2020 00:01' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '09 Nov 2020 23:59' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

**TIMEPOINT**

| Audit                                    | User   | Time (GMT)           |
|------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.    | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered 'Day 89' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '12 Nov 2020 00:01' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '16 Nov 2020 23:59' | System | 19 Nov 2020 22:22:31 |

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

**Form:** Safety Follow Up Diary

**Generated On:** 26 Nov 2020 09:35:30

**TIMEPOINT**

| Audit                                    | User   | Time (GMT)           |
|------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.    | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered 'Day 96' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[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 (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-11-21T14:23:43', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '2e93d0f2-ff6a-4b4f-b98f-ae533dd17a9e' User entered 'No (N)' | System | 21 Nov 2020 20:24:15 |
|                                                                                                                                                                                                                                                                                      | System | 21 Nov 2020 20:24:15 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

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 (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-11-21T14:24:02', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '2e93d0f2-ff6a-4b4f-b98f-ae533dd17a9e' User entered 'No (N)' | System | 21 Nov 2020 20:24:15 |



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Date and time of submission](#)

| Audit                                                                                                                                                                                                                                                                                              | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-11-21T14:24:12', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '2e93d0f2-ff6a-4b4f-b98f-ae533dd17a9e' User entered '21 Nov 2020 14:24:12' | System | 21 Nov 2020 20:24:15 |
|                                                                                                                                                                                                                                                                                                    | System | 21 Nov 2020 20:24:15 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '19 Nov 2020 00:01' | System | 19 Nov 2020 22:22:31 |

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '23 Nov 2020 23:59' | System | 19 Nov 2020 22:22:31 |

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered 'Day 103' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '26 Nov 2020 00:01' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '30 Nov 2020 23:59' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered 'Day 110' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '03 Dec 2020 00:01' | System | 19 Nov 2020 22:22:31 |



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '07 Dec 2020 23:59' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered 'Day 117' | System | 19 Nov 2020 22:22:31 |

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '10 Dec 2020 00:01' | System | 19 Nov 2020 22:22:31 |

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '14 Dec 2020 23:59' | System | 19 Nov 2020 22:22:31 |

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered 'Day 124' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '17 Dec 2020 00:01' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '21 Dec 2020 23:59' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered 'Day 131' | System | 19 Nov 2020 22:22:31 |



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '24 Dec 2020 00:01' | System | 19 Nov 2020 22:22:31 |

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '28 Dec 2020 23:59' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered 'Day 138' | System | 19 Nov 2020 22:22:31 |

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '31 Dec 2020 00:01' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '04 Jan 2021 23:59' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered 'Day 145' | System | 19 Nov 2020 22:22:31 |

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '07 Jan 2021 00:01' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '11 Jan 2021 23:59' | System | 19 Nov 2020 22:22:31 |



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered 'Day 152' | System | 19 Nov 2020 22:22:31 |

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '14 Jan 2021 00:01' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '18 Jan 2021 23:59' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered 'Day 159' | System | 19 Nov 2020 22:22:31 |

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '21 Jan 2021 00:01' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '25 Jan 2021 23:59' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered 'Day 166' | System | 19 Nov 2020 22:22:31 |

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '28 Jan 2021 00:01' | System | 19 Nov 2020 22:22:31 |



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '01 Feb 2021 23:59' | System | 19 Nov 2020 22:22:31 |

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:30

[TIMEPOINT](#)

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered 'Day 173' | System | 19 Nov 2020 22:22:31 |

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '04 Feb 2021 00:01' | System | 19 Nov 2020 22:22:31 |

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '08 Feb 2021 23:59' | System | 19 Nov 2020 22:22:31 |

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered 'Day 180' | System | 19 Nov 2020 22:22:31 |

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '11 Feb 2021 00:01' | System | 19 Nov 2020 22:22:31 |

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '15 Feb 2021 23:59' | System | 19 Nov 2020 22:22:31 |

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered 'Day 187' | System | 19 Nov 2020 22:22:31 |



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '18 Feb 2021 00:01' | System | 19 Nov 2020 22:22:31 |

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '22 Feb 2021 23:59' | System | 19 Nov 2020 22:22:31 |

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

**Form:** Safety Follow Up Diary

**Generated On:** 26 Nov 2020 09:35:30

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered 'Day 194' | System | 19 Nov 2020 22:22:31 |

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '25 Feb 2021 00:01' | System | 19 Nov 2020 22:22:31 |

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '01 Mar 2021 23:59' | System | 19 Nov 2020 22:22:31 |

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered 'Day 201' | System | 19 Nov 2020 22:22:31 |

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '04 Mar 2021 00:01' | System | 19 Nov 2020 22:22:31 |

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '08 Mar 2021 23:59' | System | 19 Nov 2020 22:22:31 |



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered 'Day 208' | System | 19 Nov 2020 22:22:31 |

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '11 Mar 2021 00:01' | System | 19 Nov 2020 22:22:31 |

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '15 Mar 2021 23:59' | System | 19 Nov 2020 22:22:31 |

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered 'Day 215' | System | 19 Nov 2020 22:22:31 |

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '18 Mar 2021 00:01' | System | 19 Nov 2020 22:22:31 |

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '22 Mar 2021 23:59' | System | 19 Nov 2020 22:22:31 |

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered 'Day 222' | System | 19 Nov 2020 22:22:31 |

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

**Form: Safety Follow Up Diary**

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| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '25 Mar 2021 00:01' | System | 19 Nov 2020 22:22:31 |



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| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '29 Mar 2021 23:59' | System | 19 Nov 2020 22:22:31 |

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered 'Day 229' | System | 19 Nov 2020 22:22:31 |

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '01 Apr 2021 00:01' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '05 Apr 2021 23:59' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered 'Day 236' | System | 19 Nov 2020 22:22:31 |

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '08 Apr 2021 00:01' | System | 19 Nov 2020 22:22:31 |

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '12 Apr 2021 23:59' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form:** Safety Follow Up Diary

**Generated On:** 26 Nov 2020 09:35:30

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered 'Day 243' | System | 19 Nov 2020 22:22:31 |



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '15 Apr 2021 00:01' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '19 Apr 2021 23:59' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered 'Day 250' | System | 19 Nov 2020 22:22:31 |

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '22 Apr 2021 00:01' | System | 19 Nov 2020 22:22:31 |

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

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| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '26 Apr 2021 23:59' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered 'Day 257' | System | 19 Nov 2020 22:22:31 |

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '29 Apr 2021 00:01' | System | 19 Nov 2020 22:22:31 |

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

**Form: Safety Follow Up Diary**

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[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '03 May 2021 23:59' | System | 19 Nov 2020 22:22:31 |



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**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered 'Day 264' | System | 19 Nov 2020 22:22:31 |

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '06 May 2021 00:01' | System | 19 Nov 2020 22:22:31 |

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '10 May 2021 23:59' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered 'Day 271' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '13 May 2021 00:01' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '17 May 2021 23:59' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered 'Day 278' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '20 May 2021 00:01' | System | 19 Nov 2020 22:22:31 |



US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '24 May 2021 23:59' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered 'Day 285' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '27 May 2021 00:01' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '31 May 2021 23:59' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered 'Day 292' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '03 Jun 2021 00:01' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '07 Jun 2021 23:59' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered 'Day 299' | System | 19 Nov 2020 22:22:31 |



US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '10 Jun 2021 00:01' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '14 Jun 2021 23:59' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered 'Day 306' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '17 Jun 2021 00:01' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '21 Jun 2021 23:59' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered 'Day 313' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '24 Jun 2021 00:01' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '28 Jun 2021 23:59' | System | 19 Nov 2020 22:22:31 |



US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered 'Day 320' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '01 Jul 2021 00:01' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '05 Jul 2021 23:59' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered 'Day 327' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '08 Jul 2021 00:01' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '12 Jul 2021 23:59' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered 'Day 334' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '15 Jul 2021 00:01' | System | 19 Nov 2020 22:22:31 |



US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '19 Jul 2021 23:59' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered 'Day 341' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '22 Jul 2021 00:01' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '26 Jul 2021 23:59' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered 'Day 348' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '29 Jul 2021 00:01' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '02 Aug 2021 23:59' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered 'Day 355' | System | 19 Nov 2020 22:22:31 |



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '05 Aug 2021 00:01' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '09 Aug 2021 23:59' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered 'Day 362' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '12 Aug 2021 00:01' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '16 Aug 2021 23:59' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered 'Day 369' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '19 Aug 2021 00:01' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '23 Aug 2021 23:59' | System | 19 Nov 2020 22:22:31 |



US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered 'Day 376' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '26 Aug 2021 00:01' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '30 Aug 2021 23:59' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered 'Day 383' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '02 Sep 2021 00:01' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '06 Sep 2021 23:59' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered 'Day 390' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '09 Sep 2021 00:01' | System | 19 Nov 2020 22:22:31 |



US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '13 Sep 2021 23:59' | System | 19 Nov 2020 22:22:31 |

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:30

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered 'Day 397' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '16 Sep 2021 00:01' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '20 Sep 2021 23:59' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered 'Day 404' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '23 Sep 2021 00:01' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '27 Sep 2021 23:59' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered 'Day 411' | System | 19 Nov 2020 22:22:31 |



US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '30 Sep 2021 00:01' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '04 Oct 2021 23:59' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered 'Day 418' | System | 19 Nov 2020 22:22:31 |

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '07 Oct 2021 00:01' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '11 Oct 2021 23:59' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered 'Day 425' | System | 19 Nov 2020 22:22:31 |

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '14 Oct 2021 00:01' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '18 Oct 2021 23:59' | System | 19 Nov 2020 22:22:31 |



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered 'Day 432' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '21 Oct 2021 00:01' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '25 Oct 2021 23:59' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form:** Safety Follow Up Diary

**Generated On:** 26 Nov 2020 09:35:30

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered 'Day 439' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '28 Oct 2021 00:01' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '01 Nov 2021 23:59' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered 'Day 446' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '04 Nov 2021 00:01' | System | 19 Nov 2020 22:22:31 |



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '08 Nov 2021 23:59' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form:** Safety Follow Up Diary

**Generated On:** 26 Nov 2020 09:35:30

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered 'Day 453' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '11 Nov 2021 00:01' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '15 Nov 2021 23:59' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered 'Day 460' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '18 Nov 2021 00:01' | System | 19 Nov 2020 22:22:31 |

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '22 Nov 2021 23:59' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered 'Day 467' | System | 19 Nov 2020 22:22:31 |



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '25 Nov 2021 00:01' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '29 Nov 2021 23:59' | System | 19 Nov 2020 22:22:31 |

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered 'Day 474' | System | 19 Nov 2020 22:22:31 |

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '02 Dec 2021 00:01' | System | 19 Nov 2020 22:22:31 |

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '06 Dec 2021 23:59' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered 'Day 481' | System | 19 Nov 2020 22:22:31 |

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '09 Dec 2021 00:01' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '13 Dec 2021 23:59' | System | 19 Nov 2020 22:22:31 |



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered 'Day 488' | System | 19 Nov 2020 22:22:31 |

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '16 Dec 2021 00:01' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '20 Dec 2021 23:59' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered 'Day 495' | System | 19 Nov 2020 22:22:31 |

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '23 Dec 2021 00:01' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '27 Dec 2021 23:59' | System | 19 Nov 2020 22:22:31 |

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

**Form:** Safety Follow Up Diary

**Generated On:** 26 Nov 2020 09:35:30

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered 'Day 502' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '30 Dec 2021 00:01' | System | 19 Nov 2020 22:22:31 |



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '03 Jan 2022 23:59' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered 'Day 509' | System | 19 Nov 2020 22:22:31 |

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '06 Jan 2022 00:01' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '10 Jan 2022 23:59' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered 'Day 516' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '13 Jan 2022 00:01' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '17 Jan 2022 23:59' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered 'Day 523' | System | 19 Nov 2020 22:22:31 |



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '20 Jan 2022 00:01' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '24 Jan 2022 23:59' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered 'Day 530' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '27 Jan 2022 00:01' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '31 Jan 2022 23:59' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered 'Day 537' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '03 Feb 2022 00:01' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '07 Feb 2022 23:59' | System | 19 Nov 2020 22:22:31 |



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered 'Day 544' | System | 19 Nov 2020 22:22:31 |

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '10 Feb 2022 00:01' | System | 19 Nov 2020 22:22:31 |

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

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| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '14 Feb 2022 23:59' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered 'Day 551' | System | 19 Nov 2020 22:22:31 |

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '17 Feb 2022 00:01' | System | 19 Nov 2020 22:22:31 |

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '21 Feb 2022 23:59' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered 'Day 558' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '24 Feb 2022 00:01' | System | 19 Nov 2020 22:22:31 |



US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '28 Feb 2022 23:59' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered 'Day 565' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '03 Mar 2022 00:01' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '07 Mar 2022 23:59' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered 'Day 572' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '10 Mar 2022 00:01' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '14 Mar 2022 23:59' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered 'Day 579' | System | 19 Nov 2020 22:22:31 |



US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '17 Mar 2022 00:01' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '21 Mar 2022 23:59' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered 'Day 586' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '24 Mar 2022 00:01' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '28 Mar 2022 23:59' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered 'Day 593' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '31 Mar 2022 00:01' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '04 Apr 2022 23:59' | System | 19 Nov 2020 22:22:31 |



US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered 'Day 600' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '07 Apr 2022 00:01' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '11 Apr 2022 23:59' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered 'Day 607' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '14 Apr 2022 00:01' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '18 Apr 2022 23:59' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form:** Safety Follow Up Diary

**Generated On:** 26 Nov 2020 09:35:30

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered 'Day 614' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '21 Apr 2022 00:01' | System | 19 Nov 2020 22:22:31 |



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '25 Apr 2022 23:59' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered 'Day 621' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '28 Apr 2022 00:01' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '02 May 2022 23:59' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered 'Day 628' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '05 May 2022 00:01' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '09 May 2022 23:59' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered 'Day 635' | System | 19 Nov 2020 22:22:31 |



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '12 May 2022 00:01' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '16 May 2022 23:59' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered 'Day 642' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '19 May 2022 00:01' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '23 May 2022 23:59' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered 'Day 649' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '26 May 2022 00:01' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '30 May 2022 23:59' | System | 19 Nov 2020 22:22:31 |



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

**Form:** Safety Follow Up Diary

**Generated On:** 26 Nov 2020 09:35:30

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered 'Day 656' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '02 Jun 2022 00:01' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '06 Jun 2022 23:59' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered 'Day 663' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '09 Jun 2022 00:01' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '13 Jun 2022 23:59' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered 'Day 670' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '16 Jun 2022 00:01' | System | 19 Nov 2020 22:22:31 |



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '20 Jun 2022 23:59' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered 'Day 677' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '23 Jun 2022 00:01' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '27 Jun 2022 23:59' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered 'Day 684' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '30 Jun 2022 00:01' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '04 Jul 2022 23:59' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered 'Day 691' | System | 19 Nov 2020 22:22:31 |



US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '07 Jul 2022 00:01' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '11 Jul 2022 23:59' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered 'Day 698' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '14 Jul 2022 00:01' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '18 Jul 2022 23:59' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered 'Day 705' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '21 Jul 2022 00:01' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '25 Jul 2022 23:59' | System | 19 Nov 2020 22:22:31 |



US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered 'Day 712' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '28 Jul 2022 00:01' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '01 Aug 2022 23:59' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered 'Day 719' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '04 Aug 2022 00:01' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '08 Aug 2022 23:59' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered 'Day 726' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '11 Aug 2022 00:01' | System | 19 Nov 2020 22:22:31 |



US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '15 Aug 2022 23:59' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered 'Day 733' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '18 Aug 2022 00:01' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '22 Aug 2022 23:59' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered 'Day 740' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '25 Aug 2022 00:01' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '29 Aug 2022 23:59' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered 'Day 747' | System | 19 Nov 2020 22:22:31 |



US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '01 Sep 2022 00:01' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '05 Sep 2022 23:59' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered 'Day 754' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '08 Sep 2022 00:01' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '12 Sep 2022 23:59' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered 'Day 761' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '15 Sep 2022 00:01' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '19 Sep 2022 23:59' | System | 19 Nov 2020 22:22:31 |



US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered 'Day 768' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '22 Sep 2022 00:01' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '26 Sep 2022 23:59' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered 'Day 775' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '29 Sep 2022 00:01' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '03 Oct 2022 23:59' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form:** Safety Follow Up Diary

**Generated On:** 26 Nov 2020 09:35:30

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered 'Day 782' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '06 Oct 2022 00:01' | System | 19 Nov 2020 22:22:31 |



US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '10 Oct 2022 23:59' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered 'Day 789' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '13 Oct 2022 00:01' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '17 Oct 2022 23:59' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered 'Day 796' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '20 Oct 2022 00:01' | System | 19 Nov 2020 22:22:31 |

US3532063

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:30**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:22:31 |
| Amendment Manager: User entered '24 Oct 2022 23:59' | System | 19 Nov 2020 22:22:31 |

US3532063

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 09:35:30**

[Was Contact Attempted?](#)

| Audit                  | User                              | Time (GMT)           |
|------------------------|-----------------------------------|----------------------|
| User entered 'Yes (Y)' | Kathy Stephens (b) (4)<br>(b) (4) | 09 Nov 2020 18:22:01 |



US3532063

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 09:35:30**

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

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| User entered '9 Nov 2020' | Kathy Stephens (b) (4)<br>(b) (4) | 09 Nov 2020 18:22:01 |

US3532063

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 09:35:30**

[Please select one status for the follow-up contact](#)

| Audit                                      | User                              | Time (GMT)           |
|--------------------------------------------|-----------------------------------|----------------------|
| User entered 'Contact Made (CONTACT MADE)' | Kathy Stephens (b) (4)<br>(b) (4) | 09 Nov 2020 18:22:01 |

US3532063

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 09:35:30**

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit               | User                              | Time (GMT)           |
|---------------------|-----------------------------------|----------------------|
| User entered empty. | Kathy Stephens (b) (4)<br>(b) (4) | 09 Nov 2020 18:22:01 |

US3532063

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 09:35:30**

[Is the participant continuing to the next visit?](#)

| Audit                  | User                              | Time (GMT)           |
|------------------------|-----------------------------------|----------------------|
| User entered 'Yes (Y)' | Kathy Stephens (b) (4)<br>(b) (4) | 09 Nov 2020 18:22:12 |

US3532063

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 09:35:30**

[Continuing Flag](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 09 Nov 2020 18:22:12 |

US3532063

**Folder:** Adverse Events

**Form:** Adverse Events Summary

**Generated On:** 26 Nov 2020 09:35:30

[Did the participant experience any adverse events?](#)

| Audit                  | User                              | Time (GMT)           |
|------------------------|-----------------------------------|----------------------|
| User entered 'Yes (Y)' | Kathy Stephens (b) (4)<br>(b) (4) | 03 Nov 2020 22:32:04 |

US3532063

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:35:30

[AEID](#)

| Audit                                                 | User             | Time (GMT)           |
|-------------------------------------------------------|------------------|----------------------|
| Reviewed for Safety.                                  | (b) (4), (b) (6) | 04 Nov 2020 17:43:32 |
|                                                       |                  |                      |
| User entered<br>'USA-US077-2020-mRNA-1273-P301000007' | System           | 04 Nov 2020 17:43:27 |
| User entered 'New'                                    | (b) (4), (b) (6) | 04 Nov 2020 17:43:27 |
|                                                       |                  |                      |
|                                                       |                  |                      |

US3532063

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:35:30

[Adverse event](#)

| Audit                                                                                                                                                                                                              | User                              | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------|----------------------|
| User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Bone and joint injuries, HLT: Limb fractures and dislocations, PT: Femur fracture, LLT: Fracture femur - version MedDRA\\23.0. | Coder Import (b) (4)<br>(b) (4)   | 03 Nov 2020 23:07:26 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.                                                                                                                            | Coder Import (b) (4)<br>(b) (4)   | 03 Nov 2020 23:07:26 |
| Data point term sent to Coder                                                                                                                                                                                      | System                            | 03 Nov 2020 22:42:36 |
| User entered 'Fractured femur'                                                                                                                                                                                     | Kathy Stephens (b) (4)<br>(b) (4) | 03 Nov 2020 22:42:22 |



US3532063

**Folder:** Adverse Events

**Form:** Adverse Events (1)

**Generated On:** 26 Nov 2020 09:35:30

[Was this a medically-attended AE?](#)

| Audit                  | User                              | Time (GMT)           |
|------------------------|-----------------------------------|----------------------|
| User entered 'Yes (Y)' | Kathy Stephens (b) (4)<br>(b) (4) | 03 Nov 2020 22:42:22 |

US3532063

**Folder:** Adverse Events

**Form:** Adverse Events (1)

**Generated On:** 26 Nov 2020 09:35:30

[Was this a Solicited Adverse Reaction?](#)

| Audit                 | User                              | Time (GMT)           |
|-----------------------|-----------------------------------|----------------------|
| User entered 'No (N)' | Kathy Stephens (b) (4)<br>(b) (4) | 03 Nov 2020 22:42:22 |

US3532063

**Folder:** Adverse Events

**Form:** Adverse Events (1)

**Generated On:** 26 Nov 2020 09:35:30

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit                 | User                              | Time (GMT)           |
|-----------------------|-----------------------------------|----------------------|
| User entered 'No (N)' | Kathy Stephens (b) (4)<br>(b) (4) | 03 Nov 2020 22:42:22 |

US3532063

**Folder:** Adverse Events

**Form:** Adverse Events (1)

**Generated On:** 26 Nov 2020 09:35:30

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                              | Time (GMT)           |
|----------------------------|-----------------------------------|----------------------|
| User entered '28 Oct 2020' | Kathy Stephens (b) (4)<br>(b) (4) | 03 Nov 2020 22:42:22 |

US3532063

**Folder:** Adverse Events

**Form:** Adverse Events (1)

**Generated On:** 26 Nov 2020 09:35:30

[Start time \(00:00-23:59\)](#)

| Audit               | User                              | Time (GMT)           |
|---------------------|-----------------------------------|----------------------|
| User entered empty. | Kathy Stephens (b) (4)<br>(b) (4) | 03 Nov 2020 22:42:22 |

US3532063

**Folder:** Adverse Events

**Form:** Adverse Events (1)

**Generated On:** 26 Nov 2020 09:35:30

[AE start date and time \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 03 Nov 2020 22:42:22 |

US3532063

**Folder:** Adverse Events

**Form:** Adverse Events (1)

**Generated On:** 26 Nov 2020 09:35:30

[Ongoing?](#)

| Audit                  | User                              | Time (GMT)           |
|------------------------|-----------------------------------|----------------------|
| User entered 'Yes (Y)' | Kathy Stephens (b) (4)<br>(b) (4) | 03 Nov 2020 22:42:22 |

US3532063

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:35:30

If not Ongoing, end date (dd MMM yyyy)

| Audit                                                                                                                                                                                                                                        | User                              | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------|----------------------|
| 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)                  | 23 Nov 2020 15:37:13 |
| Query 'Re-issue 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.' canceled (Site from Safety).                            | (b) (4), (b) (6)                  | 23 Nov 2020 15:36:53 |
| User opened query 'Re-issue 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)                  | 23 Nov 2020 15:36:40 |
| 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)                  | 16 Nov 2020 23:42:00 |
| 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 'Healing. No new baseline yet' (Site from Safety). | Kathy Stephens (b) (4)<br>(b) (4) | 13 Nov 2020 22:38:01 |
| 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 Nov 2020 13:25:13 |
| User entered empty.                                                                                                                                                                                                                          | Kathy Stephens (b) (4)<br>(b) (4) | 03 Nov 2020 22:42:22 |



US3532063

**Folder:** Adverse Events

**Form:** Adverse Events (1)

**Generated On:** 26 Nov 2020 09:35:30

[End time \(00:00-23:59\)](#)

| Audit               | User                              | Time (GMT)           |
|---------------------|-----------------------------------|----------------------|
| User entered empty. | Kathy Stephens (b) (4)<br>(b) (4) | 03 Nov 2020 22:42:22 |

US3532063

**Folder:** Adverse Events

**Form:** Adverse Events (1)

**Generated On:** 26 Nov 2020 09:35:30

[AE End Date and Time \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 03 Nov 2020 22:42:22 |

US3532063

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:35:30

[Severity](#)

| Audit                                               | User                   | Time (GMT)           |
|-----------------------------------------------------|------------------------|----------------------|
| User entered 'Grade 4 (Grade 4)' reason for change: | Kathy Stephens (b) (4) | 17 Nov 2020 01:47:19 |
| Data Entry Error                                    | (b) (4)                |                      |
| User entered 'Grade 3/Severe (Grade 3/Severe)'      | Kathy Stephens (b) (4) | 03 Nov 2020 22:42:22 |
|                                                     | (b) (4)                |                      |

US3532063

**Folder:** Adverse Events

**Form:** Adverse Events (1)

**Generated On:** 26 Nov 2020 09:35:30

[Is the adverse event serious?](#)

| Audit                  | User                              | Time (GMT)           |
|------------------------|-----------------------------------|----------------------|
| User entered 'Yes (Y)' | Kathy Stephens (b) (4)<br>(b) (4) | 03 Nov 2020 22:42:22 |

US3532063

**Folder:** Adverse Events

**Form:** Adverse Events (1)

**Generated On:** 26 Nov 2020 09:35:30

[Death](#)

| Audit            | User                              | Time (GMT)           |
|------------------|-----------------------------------|----------------------|
| User entered '0' | Kathy Stephens (b) (4)<br>(b) (4) | 03 Nov 2020 22:42:22 |

US3532063

**Folder:** Adverse Events

**Form:** Adverse Events (1)

**Generated On:** 26 Nov 2020 09:35:30

[Life threatening](#)

| Audit            | User                              | Time (GMT)           |
|------------------|-----------------------------------|----------------------|
| User entered '0' | Kathy Stephens (b) (4)<br>(b) (4) | 03 Nov 2020 22:42:22 |

US3532063

**Folder:** Adverse Events

**Form:** Adverse Events (1)

**Generated On:** 26 Nov 2020 09:35:30

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit            | User                              | Time (GMT)           |
|------------------|-----------------------------------|----------------------|
| User entered '1' | Kathy Stephens (b) (4)<br>(b) (4) | 03 Nov 2020 22:42:22 |

US3532063

**Folder:** Adverse Events

**Form:** Adverse Events (1)

**Generated On:** 26 Nov 2020 09:35:30

[Hospital Admission Date \(dd MMM yyyy\)](#)

| Audit                      | User                              | Time (GMT)           |
|----------------------------|-----------------------------------|----------------------|
| User entered '28 Oct 2020' | Kathy Stephens (b) (4)<br>(b) (4) | 03 Nov 2020 22:42:22 |



US3532063

**Folder:** Adverse Events

**Form:** Adverse Events (1)

**Generated On:** 26 Nov 2020 09:35:30

[Hospital Discharge Date \(dd MMM yyyy\)](#)

| Audit                      | User                              | Time (GMT)           |
|----------------------------|-----------------------------------|----------------------|
| User entered '01 Nov 2020' | Kathy Stephens (b) (4)<br>(b) (4) | 03 Nov 2020 22:42:22 |

US3532063

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:35:30

[Admitted to ICU?](#)

| Audit                                                                                                                                                                                                                | User                   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------|----------------------|
| User closed query 'Per CDM: Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from DM).                         | (b) (4), (b) (6)       | 13 Nov 2020 10:08:43 |
| Query 'Per CDM: Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' answered with 'updated per subject' (Site from DM). | Kathy Stephens (b) (4) | 12 Nov 2020 14:31:54 |
| User entered 'No (N)' reason for change: Data Entry Error                                                                                                                                                            | (b) (4)                | 12 Nov 2020 14:31:25 |
| User opened query 'Per CDM: Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from DM).                         | (b) (4), (b) (6)       | 12 Nov 2020 05:19:04 |
| User closed query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).                              | (b) (4), (b) (6)       | 12 Nov 2020 05:18:33 |
| Query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' answered with 'obtaining records' (Site from System).        | Kathy Stephens (b) (4) | 03 Nov 2020 22:42:43 |
| User opened query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).                              | System                 | 03 Nov 2020 22:42:22 |
| User entered 'Unknown (UNK)'                                                                                                                                                                                         | Kathy Stephens (b) (4) | 03 Nov 2020 22:42:22 |

US3532063

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:35:30

[Number of Days in ICU](#)

| Audit               | User                              | Time (GMT)           |
|---------------------|-----------------------------------|----------------------|
| User entered empty. | Kathy Stephens (b) (4)<br>(b) (4) | 03 Nov 2020 22:42:22 |

US3532063

**Folder:** Adverse Events

**Form:** Adverse Events (1)

**Generated On:** 26 Nov 2020 09:35:30

[Persistent or significant disability or incapacity](#)

| Audit            | User                              | Time (GMT)           |
|------------------|-----------------------------------|----------------------|
| User entered '0' | Kathy Stephens (b) (4)<br>(b) (4) | 03 Nov 2020 22:42:22 |

US3532063

**Folder:** Adverse Events

**Form:** Adverse Events (1)

**Generated On:** 26 Nov 2020 09:35:30

[Congenital anomaly or birth defect](#)

| Audit            | User                              | Time (GMT)           |
|------------------|-----------------------------------|----------------------|
| User entered '0' | Kathy Stephens (b) (4)<br>(b) (4) | 03 Nov 2020 22:42:22 |

US3532063

**Folder:** Adverse Events

**Form:** Adverse Events (1)

**Generated On:** 26 Nov 2020 09:35:30

[Other medically important event](#)

| Audit            | User                              | Time (GMT)           |
|------------------|-----------------------------------|----------------------|
| User entered '0' | Kathy Stephens (b) (4)<br>(b) (4) | 03 Nov 2020 22:42:22 |

US3532063

**Folder:** Adverse Events

**Form:** Adverse Events (1)

**Generated On:** 26 Nov 2020 09:35:30

[Relationship to investigational product](#)

| Audit                                    | User                              | Time (GMT)           |
|------------------------------------------|-----------------------------------|----------------------|
| User entered 'Not Related (NOT RELATED)' | Kathy Stephens (b) (4)<br>(b) (4) | 03 Nov 2020 22:42:22 |

US3532063

**Folder:** Adverse Events

**Form:** Adverse Events (1)

**Generated On:** 26 Nov 2020 09:35:30

[Relationship to Study Procedure](#)

| Audit                                    | User                              | Time (GMT)           |
|------------------------------------------|-----------------------------------|----------------------|
| User entered 'Not Related (NOT RELATED)' | Kathy Stephens (b) (4)<br>(b) (4) | 03 Nov 2020 22:42:22 |



US3532063

**Folder:** Adverse Events

**Form:** Adverse Events (1)

**Generated On:** 26 Nov 2020 09:35:30

[Action taken with investigational product](#)

| Audit                                          | User                              | Time (GMT)           |
|------------------------------------------------|-----------------------------------|----------------------|
| User entered 'Not Applicable (NOT APPLICABLE)' | Kathy Stephens (b) (4)<br>(b) (4) | 03 Nov 2020 22:42:22 |

US3532063

**Folder:** Adverse Events

**Form:** Adverse Events (1)

**Generated On:** 26 Nov 2020 09:35:30

[None](#)

| Audit            | User                              | Time (GMT)           |
|------------------|-----------------------------------|----------------------|
| User entered '0' | Kathy Stephens (b) (4)<br>(b) (4) | 03 Nov 2020 22:42:22 |

US3532063

**Folder:** Adverse Events

**Form:** Adverse Events (1)

**Generated On:** 26 Nov 2020 09:35:30

[Concomitant Medication](#)

| Audit            | User                              | Time (GMT)           |
|------------------|-----------------------------------|----------------------|
| User entered '1' | Kathy Stephens (b) (4)<br>(b) (4) | 03 Nov 2020 22:42:22 |

US3532063

**Folder:** Adverse Events

**Form:** Adverse Events (1)

**Generated On:** 26 Nov 2020 09:35:30

[Concomitant Procedure](#)

| Audit            | User                              | Time (GMT)           |
|------------------|-----------------------------------|----------------------|
| User entered '1' | Kathy Stephens (b) (4)<br>(b) (4) | 03 Nov 2020 22:42:22 |

US3532063

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 09:35:30**

[Outcome](#)

| Audit                                                                                                                                                                                                                                    | User                   | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------|----------------------|
| 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 Nov 2020 13:25:04 |
| User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'                                                                                                                                                                               | Kathy Stephens (b) (4) | 03 Nov 2020 22:42:22 |

US3532063

**Folder:** Adverse Events

**Form:** Adverse Events (1)

**Generated On:** 26 Nov 2020 09:35:30

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

| Audit               | User                              | Time (GMT)           |
|---------------------|-----------------------------------|----------------------|
| User entered empty. | Kathy Stephens (b) (4)<br>(b) (4) | 03 Nov 2020 22:42:22 |

US3532063

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:35:30

[Narrative](#)

| Audit                                                                                                                                                                                                                | User                              | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------|----------------------|
| User entered 'WHILE OUT OF TOWN, SUBJECT FELL AND FRACTURED L FEMUR. HOSPITALIZED AND SURGICALLY REPAIRED. HAS BEEN DISCHARGED FOR REHAB AND IS STILL OUT OF STATE. WILL OBTAIN HOSPITAL RECORDS                     | Kathy Stephens (b) (4)<br>(b) (4) | 17 Nov 2020 23:41:18 |
| RECORDS provided 11-17-20' reason for change:<br>Data Entry Error                                                                                                                                                    |                                   |                      |
| User entered 'WHILE OUT OF TOWN, SUBJECT FELL AND FRACTURED L FEMUR. HOSPITALIZED AND SURGICALLY REPAIRED. HAS BEEN DISCHARGED FOR REHAB AND IS STILL OUT OF STATE. WILL OBTAIN HOSPITAL RECORDS                     | Kathy Stephens (b) (4)<br>(b) (4) | 17 Nov 2020 22:54:37 |
| Records being sent.' reason for change: Data Entry Error                                                                                                                                                             |                                   |                      |
| User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).                                       | (b) (4), (b) (6)                  | 16 Nov 2020 23:42:15 |
| User closed query 'PV Query: What was the reason for the fall? (i.e. mechanical, accidental, underlying condition, etc)' (Site from Safety).                                                                         | (b) (4), (b) (6)                  | 16 Nov 2020 23:42:12 |
| Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'no hospital records available yet' (Site from Safety). | Kathy Stephens (b) (4)<br>(b) (4) | 13 Nov 2020 23:08:18 |
| Query 'PV Query: What was the reason for the fall? (i.e. mechanical, accidental, underlying condition, etc)' answered with 'Accidental - Wet pavement and her dog on a leash.' (Site from Safety).                   | Kathy Stephens (b) (4)<br>(b) (4) | 13 Nov 2020 23:07:56 |
| User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).                                       | (b) (4), (b) (6)                  | 13 Nov 2020 13:25:31 |
| User opened query 'PV Query: What was the reason for the fall? (i.e. mechanical, accidental, underlying condition, etc)' (Site from Safety).                                                                         | (b) (4), (b) (6)                  | 13 Nov 2020 13:25:24 |

US3532063

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 09:35:30**

[Narrative](#)

| Audit                                                                                                                                                                                             | User                   | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------|----------------------|
| User entered 'While out of town, subject fell and fractured L femur. Hospitalized and surgically repaired. Has been discharged for rehab and is still out of state. Will obtain hospital records' | Kathy Stephens (b) (4) | 03 Nov 2020 22:42:22 |



US3532063

**Folder:** Adverse Events

**Form:** Adverse Events (1)

**Generated On:** 26 Nov 2020 09:35:30

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 03 Nov 2020 22:42:22 |

US3532063

**Folder:** Adverse Events

**Form:** Adverse Events (1)

**Generated On:** 26 Nov 2020 09:35:30

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 03 Nov 2020 22:42:22 |

US3532063

**Folder:** Adverse Events

**Form:** Adverse Events (1)

**Generated On:** 26 Nov 2020 09:35:30

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '0' | System | 03 Nov 2020 22:42:22 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination Summary**

**Generated On: 26 Nov 2020 09:35:30**

[Were any prior/concomitant medications and/or vaccinations taken?](#)

| Audit                  | User                              | Time (GMT)           |
|------------------------|-----------------------------------|----------------------|
| User entered 'Yes (Y)' | Kathy Stephens (b) (4)<br>(b) (4) | 18 Aug 2020 19:00:29 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 09:35:30**

[Name of Medication](#)

| Audit                                                                                                                                          | User                              | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------|----------------------|
| User coded data point as ATC: VARIOUS, ATC: GENERAL NUTRIENTS, ATC: OTHER NUTRIENTS, PRODUCT: OMEGA-3 NOS - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4)   | 03 Sep 2020 09:16:39 |
| 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)   | 03 Sep 2020 09:16:39 |
| Data point term sent to Coder                                                                                                                  | System                            | 26 Aug 2020 17:37:05 |
| User entered 'Omega 3'                                                                                                                         | Kathy Stephens (b) (4)<br>(b) (4) | 26 Aug 2020 17:36:29 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 09:35:30**

[Prophylaxis](#)

| Audit                  | User                              | Time (GMT)           |
|------------------------|-----------------------------------|----------------------|
| User entered 'Yes (Y)' | Kathy Stephens (b) (4)<br>(b) (4) | 26 Aug 2020 17:36:29 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 09:35:30**

[Indication](#)

| Audit                 | User                              | Time (GMT)           |
|-----------------------|-----------------------------------|----------------------|
| User entered 'health' | Kathy Stephens (b) (4)<br>(b) (4) | 26 Aug 2020 17:36:29 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 09:35:30**

[Dose per administration](#)

| Audit               | User                              | Time (GMT)           |
|---------------------|-----------------------------------|----------------------|
| User entered '1200' | Kathy Stephens (b) (4)<br>(b) (4) | 26 Aug 2020 17:36:29 |



US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 09:35:30**

[Dose unit](#)

| Audit                  | User                              | Time (GMT)           |
|------------------------|-----------------------------------|----------------------|
| User entered 'mg (mg)' | Kathy Stephens (b) (4)<br>(b) (4) | 26 Aug 2020 17:36:29 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 09:35:30**

If dose unit is Other, specify

| Audit               | User                              | Time (GMT)           |
|---------------------|-----------------------------------|----------------------|
| User entered empty. | Kathy Stephens (b) (4)<br>(b) (4) | 26 Aug 2020 17:36:29 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 09:35:30**

[Frequency](#)

| Audit                          | User                              | Time (GMT)           |
|--------------------------------|-----------------------------------|----------------------|
| User entered 'once daily (QD)' | Kathy Stephens (b) (4)<br>(b) (4) | 26 Aug 2020 17:36:29 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 09:35:30**

[If frequency is Other, specify](#)

| Audit               | User                              | Time (GMT)           |
|---------------------|-----------------------------------|----------------------|
| User entered empty. | Kathy Stephens (b) (4)<br>(b) (4) | 26 Aug 2020 17:36:29 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 09:35:30**

[Route of administration](#)

| Audit                      | User                              | Time (GMT)           |
|----------------------------|-----------------------------------|----------------------|
| User entered 'Oral (ORAL)' | Kathy Stephens (b) (4)<br>(b) (4) | 26 Aug 2020 17:36:29 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 09:35:30**

If route of administration is Other, specify

| Audit               | User                              | Time (GMT)           |
|---------------------|-----------------------------------|----------------------|
| User entered empty. | Kathy Stephens (b) (4)<br>(b) (4) | 26 Aug 2020 17:36:29 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 09:35:30**

[Start date \(dd MMM yyyy\)](#)

| Audit               | User                              | Time (GMT)           |
|---------------------|-----------------------------------|----------------------|
| User entered empty. | Kathy Stephens (b) (4)<br>(b) (4) | 26 Aug 2020 17:36:29 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 09:35:30**

[Start date completely unknown](#)

| Audit            | User                              | Time (GMT)           |
|------------------|-----------------------------------|----------------------|
| User entered '1' | Kathy Stephens (b) (4)<br>(b) (4) | 26 Aug 2020 17:36:29 |



US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 09:35:30**

[Ongoing?](#)

| Audit                  | User                              | Time (GMT)           |
|------------------------|-----------------------------------|----------------------|
| User entered 'Yes (Y)' | Kathy Stephens (b) (4)<br>(b) (4) | 26 Aug 2020 17:36:29 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 09:35:30**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit               | User                              | Time (GMT)           |
|---------------------|-----------------------------------|----------------------|
| User entered empty. | Kathy Stephens (b) (4)<br>(b) (4) | 26 Aug 2020 17:36:29 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 09:35:30**

[Was this medication taken for solicited event?](#)

| Audit                 | User                              | Time (GMT)           |
|-----------------------|-----------------------------------|----------------------|
| User entered 'No (N)' | Kathy Stephens (b) (4)<br>(b) (4) | 26 Aug 2020 17:36:29 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 09:35:30**

[Separate Dosage Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 26 Aug 2020 17:36:29 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 09:35:30**

[Interval Dosage Unit Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 26 Aug 2020 17:36:29 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 09:35:30**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User   | Time (GMT)           |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 26 Aug 2020 17:36:29 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 09:35:30**

[Name of Medication](#)

| Audit                                                                                                                                                                      | User                   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------|----------------------|
| User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: CALCIUM, ATC: CALCIUM, PRODUCT: CALCIUM - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)   | 27 Aug 2020 17:53:05 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.                                                                  | Coder Import (b) (4)   | 27 Aug 2020 17:53:05 |
| Data point term sent to Coder                                                                                                                                              | System                 | 26 Aug 2020 17:38:09 |
| Data point term sent to Coder                                                                                                                                              | System                 | 26 Aug 2020 17:37:07 |
| User entered 'calcium'                                                                                                                                                     | Kathy Stephens (b) (4) | 26 Aug 2020 17:36:50 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 09:35:30**

[Prophylaxis](#)

| Audit                                                                                  | User                   | Time (GMT)           |
|----------------------------------------------------------------------------------------|------------------------|----------------------|
| User closed query 'Data is required. Please complete.' (Site from System).             | System                 | 26 Aug 2020 17:37:29 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System                 | 26 Aug 2020 17:37:29 |
| User entered 'Yes (Y)' reason for change: Data Entry Error                             | Kathy Stephens (b) (4) | 26 Aug 2020 17:37:29 |
| User opened query 'Data is required. Please complete.' (Site from System).             | System                 | 26 Aug 2020 17:36:50 |
| User entered empty.                                                                    | Kathy Stephens (b) (4) | 26 Aug 2020 17:36:50 |



US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 09:35:30**

[Indication](#)

| Audit                                                                                  | User                   | Time (GMT)           |
|----------------------------------------------------------------------------------------|------------------------|----------------------|
| User closed query 'Data is required. Please complete.' (Site from System).             | System                 | 26 Aug 2020 17:37:29 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System                 | 26 Aug 2020 17:37:29 |
| User entered 'health' reason for change: Data Entry Error                              | Kathy Stephens (b) (4) | 26 Aug 2020 17:37:29 |
| User opened query 'Data is required. Please complete.' (Site from System).             | System                 | 26 Aug 2020 17:36:50 |
| User entered empty.                                                                    | Kathy Stephens (b) (4) | 26 Aug 2020 17:36:50 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 09:35:30**

[Dose per administration](#)

| Audit                                                                                  | User                              | Time (GMT)           |
|----------------------------------------------------------------------------------------|-----------------------------------|----------------------|
| User closed query 'Data is required. Please complete.' (Site from System).             | System                            | 26 Aug 2020 17:37:29 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System                            | 26 Aug 2020 17:37:29 |
| User entered '1000' reason for change: Data Entry Error                                | Kathy Stephens (b) (4)<br>(b) (4) | 26 Aug 2020 17:37:29 |
| User opened query 'Data is required. Please complete.' (Site from System).             | System                            | 26 Aug 2020 17:36:50 |
| User entered empty.                                                                    | Kathy Stephens (b) (4)<br>(b) (4) | 26 Aug 2020 17:36:50 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 09:35:30**

[Dose unit](#)

| Audit                                                                                  | User                   | Time (GMT)           |
|----------------------------------------------------------------------------------------|------------------------|----------------------|
| User closed query 'Data is required. Please complete.' (Site from System).             | System                 | 26 Aug 2020 17:37:29 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System                 | 26 Aug 2020 17:37:29 |
| User entered 'mg (mg)' reason for change: New Information                              | Kathy Stephens (b) (4) | 26 Aug 2020 17:37:29 |
| User opened query 'Data is required. Please complete.' (Site from System).             | System                 | 26 Aug 2020 17:36:50 |
| User entered empty.                                                                    | Kathy Stephens (b) (4) | 26 Aug 2020 17:36:50 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 09:35:30**

If dose unit is Other, specify

| Audit               | User                              | Time (GMT)           |
|---------------------|-----------------------------------|----------------------|
| User entered empty. | Kathy Stephens (b) (4)<br>(b) (4) | 26 Aug 2020 17:36:50 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 09:35:30**

[Frequency](#)

| Audit                                                                                  | User                   | Time (GMT)           |
|----------------------------------------------------------------------------------------|------------------------|----------------------|
| User entered 'three times daily (TID)' reason for change: Data Entry Error             | Kathy Stephens (b) (4) | 26 Aug 2020 17:38:39 |
| User closed query 'Data is required. Please complete.' (Site from System).             | System                 | 26 Aug 2020 17:37:29 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System                 | 26 Aug 2020 17:37:29 |
| User entered 'once daily (QD)' reason for change: Data Entry Error                     | Kathy Stephens (b) (4) | 26 Aug 2020 17:37:29 |
| User opened query 'Data is required. Please complete.' (Site from System).             | System                 | 26 Aug 2020 17:36:50 |
| User entered empty.                                                                    | Kathy Stephens (b) (4) | 26 Aug 2020 17:36:50 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 09:35:30**

[If frequency is Other, specify](#)

| Audit               | User                              | Time (GMT)           |
|---------------------|-----------------------------------|----------------------|
| User entered empty. | Kathy Stephens (b) (4)<br>(b) (4) | 26 Aug 2020 17:36:50 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 09:35:30**

[Route of administration](#)

| Audit                                                                                  | User                   | Time (GMT)           |
|----------------------------------------------------------------------------------------|------------------------|----------------------|
| User closed query 'Data is required. Please complete.' (Site from System).             | System                 | 26 Aug 2020 17:37:29 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System                 | 26 Aug 2020 17:37:29 |
| User entered 'Oral (ORAL)' reason for change: Data Entry Error                         | Kathy Stephens (b) (4) | 26 Aug 2020 17:37:29 |
| User opened query 'Data is required. Please complete.' (Site from System).             | System                 | 26 Aug 2020 17:36:50 |
| User entered empty.                                                                    | Kathy Stephens (b) (4) | 26 Aug 2020 17:36:50 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 09:35:30**

If route of administration is Other, specify

| Audit               | User                              | Time (GMT)           |
|---------------------|-----------------------------------|----------------------|
| User entered empty. | Kathy Stephens (b) (4)<br>(b) (4) | 26 Aug 2020 17:36:50 |



US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 09:35:30**

[Start date \(dd MMM yyyy\)](#)

| Audit                                                                                                                           | User                              | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------|-----------------------------------|----------------------|
| User closed query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System). | System                            | 26 Aug 2020 17:39:28 |
| User opened query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System). | System                            | 26 Aug 2020 17:36:50 |
| User entered empty.                                                                                                             | Kathy Stephens (b) (4)<br>(b) (4) | 26 Aug 2020 17:36:50 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 09:35:30**

[Start date completely unknown](#)

| Audit                                                | User                                         | Time (GMT)           |
|------------------------------------------------------|----------------------------------------------|----------------------|
| User entered '1' reason for change: Data Entry Error | Kathy Stephens (b) (4)                       | 26 Aug 2020 17:39:28 |
| User entered '0'                                     | (b) (4)<br>Kathy Stephens (b) (4)<br>(b) (4) | 26 Aug 2020 17:36:50 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 09:35:30**

[Ongoing?](#)

| Audit                                                                                  | User                   | Time (GMT)           |
|----------------------------------------------------------------------------------------|------------------------|----------------------|
| User closed query 'Data is required. Please complete.' (Site from System).             | System                 | 26 Aug 2020 17:37:29 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System                 | 26 Aug 2020 17:37:29 |
| User entered 'Yes (Y)' reason for change: Data Entry Error                             | Kathy Stephens (b) (4) | 26 Aug 2020 17:37:29 |
| User opened query 'Data is required. Please complete.' (Site from System).             | System                 | 26 Aug 2020 17:36:50 |
| User entered empty.                                                                    | Kathy Stephens (b) (4) | 26 Aug 2020 17:36:50 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 09:35:30**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit               | User                              | Time (GMT)           |
|---------------------|-----------------------------------|----------------------|
| User entered empty. | Kathy Stephens (b) (4)<br>(b) (4) | 26 Aug 2020 17:36:50 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 09:35:30**

[Was this medication taken for solicited event?](#)

| Audit                                                                                  | User                   | Time (GMT)           |
|----------------------------------------------------------------------------------------|------------------------|----------------------|
| User closed query 'Data is required. Please complete.' (Site from System).             | System                 | 26 Aug 2020 17:37:29 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System                 | 26 Aug 2020 17:37:29 |
| User entered 'No (N)' reason for change: Data Entry Error                              | Kathy Stephens (b) (4) | 26 Aug 2020 17:37:29 |
| User opened query 'Data is required. Please complete.' (Site from System).             | System                 | 26 Aug 2020 17:36:50 |
| User entered empty.                                                                    | Kathy Stephens (b) (4) | 26 Aug 2020 17:36:50 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 09:35:30**

[Separate Dosage Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '3'    | System | 26 Aug 2020 17:38:39 |
| User entered '1'    | System | 26 Aug 2020 17:37:29 |
| User entered empty. | System | 26 Aug 2020 17:36:50 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 09:35:30**

[Interval Dosage Unit Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '1'    | System | 26 Aug 2020 17:37:29 |
| User entered empty. | System | 26 Aug 2020 17:36:50 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 09:35:30**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User   | Time (GMT)           |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 26 Aug 2020 17:37:29 |
| User entered empty.      | System | 26 Aug 2020 17:36:50 |



US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:35:30

[Name of Medication](#)

| Audit                                                                                                                                                                                         | User                              | Time (GMT)           |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------|----------------------|
| User coded data point as ATC: VARIOUS, ATC: UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE, PRODUCT: CURCUMA LONGA, PRODUCTSYNONYM: TURMERIC [CURCUMA LONGA] - version WHODrug-Global-B3\202003. | Coder Import (b) (4)<br>(b) (4)   | 30 Aug 2020 11:45:39 |
| 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)   | 30 Aug 2020 11:45:39 |
| Data point term sent to Coder                                                                                                                                                                 | System                            | 26 Aug 2020 17:39:11 |
| User entered 'tumeric'                                                                                                                                                                        | Kathy Stephens (b) (4)<br>(b) (4) | 26 Aug 2020 17:38:12 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 09:35:30**

[Prophylaxis](#)

| Audit                  | User                              | Time (GMT)           |
|------------------------|-----------------------------------|----------------------|
| User entered 'Yes (Y)' | Kathy Stephens (b) (4)<br>(b) (4) | 26 Aug 2020 17:38:12 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 09:35:30**

[Indication](#)

| Audit                 | User                              | Time (GMT)           |
|-----------------------|-----------------------------------|----------------------|
| User entered 'health' | Kathy Stephens (b) (4)<br>(b) (4) | 26 Aug 2020 17:38:12 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 09:35:30**

[Dose per administration](#)

| Audit               | User                              | Time (GMT)           |
|---------------------|-----------------------------------|----------------------|
| User entered '1000' | Kathy Stephens (b) (4)<br>(b) (4) | 26 Aug 2020 17:38:12 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 09:35:30**

[Dose unit](#)

| Audit                  | User                              | Time (GMT)           |
|------------------------|-----------------------------------|----------------------|
| User entered 'mg (mg)' | Kathy Stephens (b) (4)<br>(b) (4) | 26 Aug 2020 17:38:12 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 09:35:30**

If dose unit is Other, specify

| Audit               | User                              | Time (GMT)           |
|---------------------|-----------------------------------|----------------------|
| User entered empty. | Kathy Stephens (b) (4)<br>(b) (4) | 26 Aug 2020 17:38:12 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 09:35:30**

[Frequency](#)

| Audit                            | User                              | Time (GMT)           |
|----------------------------------|-----------------------------------|----------------------|
| User entered 'twice daily (BID)' | Kathy Stephens (b) (4)<br>(b) (4) | 26 Aug 2020 17:38:12 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 09:35:30**

[If frequency is Other, specify](#)

| Audit               | User                              | Time (GMT)           |
|---------------------|-----------------------------------|----------------------|
| User entered empty. | Kathy Stephens (b) (4)<br>(b) (4) | 26 Aug 2020 17:38:12 |



US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 09:35:30**

[Route of administration](#)

| Audit                      | User                              | Time (GMT)           |
|----------------------------|-----------------------------------|----------------------|
| User entered 'Oral (ORAL)' | Kathy Stephens (b) (4)<br>(b) (4) | 26 Aug 2020 17:38:12 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 09:35:30**

If route of administration is Other, specify

| Audit               | User                              | Time (GMT)           |
|---------------------|-----------------------------------|----------------------|
| User entered empty. | Kathy Stephens (b) (4)<br>(b) (4) | 26 Aug 2020 17:38:12 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 09:35:30**

[Start date \(dd MMM yyyy\)](#)

| Audit                                                                                                                           | User                              | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------|-----------------------------------|----------------------|
| User closed query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System). | System                            | 26 Aug 2020 17:38:23 |
| User opened query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System). | System                            | 26 Aug 2020 17:38:12 |
| User entered empty.                                                                                                             | Kathy Stephens (b) (4)<br>(b) (4) | 26 Aug 2020 17:38:12 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 09:35:30**

[Start date completely unknown](#)

| Audit                                                | User                   | Time (GMT)           |
|------------------------------------------------------|------------------------|----------------------|
| User entered '1' reason for change: Data Entry Error | Kathy Stephens (b) (4) | 26 Aug 2020 17:38:23 |
|                                                      | (b) (4)                |                      |
| User entered '0'                                     | Kathy Stephens (b) (4) | 26 Aug 2020 17:38:12 |
|                                                      | (b) (4)                |                      |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 09:35:30**

[Ongoing?](#)

| Audit                  | User                              | Time (GMT)           |
|------------------------|-----------------------------------|----------------------|
| User entered 'Yes (Y)' | Kathy Stephens (b) (4)<br>(b) (4) | 26 Aug 2020 17:38:12 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 09:35:30**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit               | User                              | Time (GMT)           |
|---------------------|-----------------------------------|----------------------|
| User entered empty. | Kathy Stephens (b) (4)<br>(b) (4) | 26 Aug 2020 17:38:12 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 09:35:30**

[Was this medication taken for solicited event?](#)

| Audit                 | User                              | Time (GMT)           |
|-----------------------|-----------------------------------|----------------------|
| User entered 'No (N)' | Kathy Stephens (b) (4)<br>(b) (4) | 26 Aug 2020 17:38:12 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 09:35:30**

[Separate Dosage Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '2' | System | 26 Aug 2020 17:38:12 |



US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 09:35:30**

[Interval Dosage Unit Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 26 Aug 2020 17:38:12 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 09:35:30**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User   | Time (GMT)           |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 26 Aug 2020 17:38:12 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 09:35:30**

[Name of Medication](#)

| Audit                                                                                                                                                                                                                                       | User                   | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------|----------------------|
| User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)   | 27 Aug 2020 17:53:49 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.                                                                                                                                   | Coder Import (b) (4)   | 27 Aug 2020 17:53:49 |
| Data point term sent to Coder                                                                                                                                                                                                               | System                 | 26 Aug 2020 17:41:21 |
| User entered 'Multi vitamin'                                                                                                                                                                                                                | Kathy Stephens (b) (4) | 26 Aug 2020 17:40:37 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 09:35:30**

[Prophylaxis](#)

| Audit                  | User                              | Time (GMT)           |
|------------------------|-----------------------------------|----------------------|
| User entered 'Yes (Y)' | Kathy Stephens (b) (4)<br>(b) (4) | 26 Aug 2020 17:40:37 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 09:35:30**

[Indication](#)

| Audit                 | User                              | Time (GMT)           |
|-----------------------|-----------------------------------|----------------------|
| User entered 'health' | Kathy Stephens (b) (4)<br>(b) (4) | 26 Aug 2020 17:40:37 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 09:35:30**

[Dose per administration](#)

| Audit            | User                              | Time (GMT)           |
|------------------|-----------------------------------|----------------------|
| User entered '1' | Kathy Stephens (b) (4)<br>(b) (4) | 26 Aug 2020 17:40:37 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 09:35:30**

[Dose unit](#)

| Audit                          | User                              | Time (GMT)           |
|--------------------------------|-----------------------------------|----------------------|
| User entered 'tablet (TABLET)' | Kathy Stephens (b) (4)<br>(b) (4) | 26 Aug 2020 17:40:37 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 09:35:30**

If dose unit is Other, specify

| Audit               | User                              | Time (GMT)           |
|---------------------|-----------------------------------|----------------------|
| User entered empty. | Kathy Stephens (b) (4)<br>(b) (4) | 26 Aug 2020 17:40:37 |



US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 09:35:30**

[Frequency](#)

| Audit                          | User                              | Time (GMT)           |
|--------------------------------|-----------------------------------|----------------------|
| User entered 'once daily (QD)' | Kathy Stephens (b) (4)<br>(b) (4) | 26 Aug 2020 17:40:37 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 09:35:30**

[If frequency is Other, specify](#)

| Audit               | User                              | Time (GMT)           |
|---------------------|-----------------------------------|----------------------|
| User entered empty. | Kathy Stephens (b) (4)<br>(b) (4) | 26 Aug 2020 17:40:37 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 09:35:30**

[Route of administration](#)

| Audit                      | User                              | Time (GMT)           |
|----------------------------|-----------------------------------|----------------------|
| User entered 'Oral (ORAL)' | Kathy Stephens (b) (4)<br>(b) (4) | 26 Aug 2020 17:40:37 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 09:35:30**

If route of administration is Other, specify

| Audit               | User                              | Time (GMT)           |
|---------------------|-----------------------------------|----------------------|
| User entered empty. | Kathy Stephens (b) (4)<br>(b) (4) | 26 Aug 2020 17:40:37 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 09:35:30**

[Start date \(dd MMM yyyy\)](#)

| Audit               | User                              | Time (GMT)           |
|---------------------|-----------------------------------|----------------------|
| User entered empty. | Kathy Stephens (b) (4)<br>(b) (4) | 26 Aug 2020 17:40:37 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 09:35:30**

[Start date completely unknown](#)

| Audit            | User                              | Time (GMT)           |
|------------------|-----------------------------------|----------------------|
| User entered '1' | Kathy Stephens (b) (4)<br>(b) (4) | 26 Aug 2020 17:40:37 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 09:35:30**

[Ongoing?](#)

| Audit                  | User                              | Time (GMT)           |
|------------------------|-----------------------------------|----------------------|
| User entered 'Yes (Y)' | Kathy Stephens (b) (4)<br>(b) (4) | 26 Aug 2020 17:40:37 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 09:35:30**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit               | User                              | Time (GMT)           |
|---------------------|-----------------------------------|----------------------|
| User entered empty. | Kathy Stephens (b) (4)<br>(b) (4) | 26 Aug 2020 17:40:37 |



US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 09:35:30**

[Was this medication taken for solicited event?](#)

| Audit                 | User                              | Time (GMT)           |
|-----------------------|-----------------------------------|----------------------|
| User entered 'No (N)' | Kathy Stephens (b) (4)<br>(b) (4) | 26 Aug 2020 17:40:37 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 09:35:30**

[Separate Dosage Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 26 Aug 2020 17:40:37 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 09:35:30**

[Interval Dosage Unit Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 26 Aug 2020 17:40:37 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 09:35:30**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User   | Time (GMT)           |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 26 Aug 2020 17:40:37 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 09:35:30**

[Name of Medication](#)

| Audit                                                                                                                                                                                                                                                                         | User                              | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------|----------------------|
| User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN B-COMPLEX, INCL. COMBINATIONS, ATC: VITAMIN B-COMPLEX, PLAIN, PRODUCT: VITAMIN B COMPLEX, PRODUCTSYNONYM: B-COMPLEX [VITAMIN B COMPLEX] - version WHODrug-Global-B3\\202003.       | Coder Import (b) (4)<br>(b) (4)   | 13 Oct 2020 12:15:33 |
| 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)   | 13 Oct 2020 12:15:33 |
| User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN B-COMPLEX, INCL. COMBINATIONS, ATC: VITAMIN B-COMPLEX, PLAIN, PRODUCT: VITAMIN B COMPLEX, PRODUCTSYNONYM: SUPER B COMPLEX [VITAMIN B COMPLEX] - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4)   | 30 Aug 2020 12:10:42 |
| 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)   | 30 Aug 2020 12:10:42 |
| Data point term sent to Coder                                                                                                                                                                                                                                                 | System                            | 26 Aug 2020 17:42:24 |
| User entered 'Super B vitamin'                                                                                                                                                                                                                                                | Kathy Stephens (b) (4)<br>(b) (4) | 26 Aug 2020 17:41:54 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 09:35:30**

[Prophylaxis](#)

| Audit                  | User                              | Time (GMT)           |
|------------------------|-----------------------------------|----------------------|
| User entered 'Yes (Y)' | Kathy Stephens (b) (4)<br>(b) (4) | 26 Aug 2020 17:41:54 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 09:35:30**

[Indication](#)

| Audit                 | User                              | Time (GMT)           |
|-----------------------|-----------------------------------|----------------------|
| User entered 'health' | Kathy Stephens (b) (4)<br>(b) (4) | 26 Aug 2020 17:41:54 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 09:35:30**

[Dose per administration](#)

| Audit                                                | User                   | Time (GMT)           |
|------------------------------------------------------|------------------------|----------------------|
| User entered '1' reason for change: Data Entry Error | Kathy Stephens (b) (4) | 26 Aug 2020 17:43:15 |
| User entered '5000`                                  | Kathy Stephens (b) (4) | 26 Aug 2020 17:41:54 |



US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 09:35:30**

[Dose unit](#)

| Audit                                                                 | User                              | Time (GMT)           |
|-----------------------------------------------------------------------|-----------------------------------|----------------------|
| User entered 'tablet (TABLET)' reason for change:<br>Data Entry Error | Kathy Stephens (b) (4)<br>(b) (4) | 26 Aug 2020 17:43:15 |
| User entered 'IU (IU)'                                                | Kathy Stephens (b) (4)<br>(b) (4) | 26 Aug 2020 17:41:54 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 09:35:30**

If dose unit is Other, specify

| Audit               | User                              | Time (GMT)           |
|---------------------|-----------------------------------|----------------------|
| User entered empty. | Kathy Stephens (b) (4)<br>(b) (4) | 26 Aug 2020 17:41:54 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 09:35:30**

[Frequency](#)

| Audit                          | User                              | Time (GMT)           |
|--------------------------------|-----------------------------------|----------------------|
| User entered 'once daily (QD)' | Kathy Stephens (b) (4)<br>(b) (4) | 26 Aug 2020 17:41:54 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 09:35:30**

[If frequency is Other, specify](#)

| Audit               | User                              | Time (GMT)           |
|---------------------|-----------------------------------|----------------------|
| User entered empty. | Kathy Stephens (b) (4)<br>(b) (4) | 26 Aug 2020 17:41:54 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 09:35:30**

[Route of administration](#)

| Audit                      | User                              | Time (GMT)           |
|----------------------------|-----------------------------------|----------------------|
| User entered 'Oral (ORAL)' | Kathy Stephens (b) (4)<br>(b) (4) | 26 Aug 2020 17:41:54 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 09:35:30**

If route of administration is Other, specify

| Audit               | User                              | Time (GMT)           |
|---------------------|-----------------------------------|----------------------|
| User entered empty. | Kathy Stephens (b) (4)<br>(b) (4) | 26 Aug 2020 17:41:54 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 09:35:30**

[Start date \(dd MMM yyyy\)](#)

| Audit               | User                              | Time (GMT)           |
|---------------------|-----------------------------------|----------------------|
| User entered empty. | Kathy Stephens (b) (4)<br>(b) (4) | 26 Aug 2020 17:41:54 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 09:35:30**

[Start date completely unknown](#)

| Audit            | User                              | Time (GMT)           |
|------------------|-----------------------------------|----------------------|
| User entered '1' | Kathy Stephens (b) (4)<br>(b) (4) | 26 Aug 2020 17:41:54 |



US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 09:35:30**

[Ongoing?](#)

| Audit                  | User                              | Time (GMT)           |
|------------------------|-----------------------------------|----------------------|
| User entered 'Yes (Y)' | Kathy Stephens (b) (4)<br>(b) (4) | 26 Aug 2020 17:41:54 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 09:35:30**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit               | User                              | Time (GMT)           |
|---------------------|-----------------------------------|----------------------|
| User entered empty. | Kathy Stephens (b) (4)<br>(b) (4) | 26 Aug 2020 17:41:54 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 09:35:30**

[Was this medication taken for solicited event?](#)

| Audit                 | User                              | Time (GMT)           |
|-----------------------|-----------------------------------|----------------------|
| User entered 'No (N)' | Kathy Stephens (b) (4)<br>(b) (4) | 26 Aug 2020 17:41:54 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 09:35:30**

[Separate Dosage Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 26 Aug 2020 17:41:54 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 09:35:30**

[Interval Dosage Unit Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 26 Aug 2020 17:41:54 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 09:35:30**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User   | Time (GMT)           |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 26 Aug 2020 17:41:54 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 09:35:30**

[Name of Medication](#)

| Audit                                                                                                                                                                                                                                                     | User                   | Time (GMT)           |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------|----------------------|
| User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: COLECALCIFEROL, PRODUCTSYNONYM: VITAMIN D3 - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)   | 27 Aug 2020 17:54:02 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.                                                                                                                                                 | Coder Import (b) (4)   | 27 Aug 2020 17:54:02 |
| Data point term sent to Coder                                                                                                                                                                                                                             | System                 | 26 Aug 2020 17:43:26 |
| User entered 'Vitamin D3'                                                                                                                                                                                                                                 | Kathy Stephens (b) (4) | 26 Aug 2020 17:42:51 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 09:35:30**

[Prophylaxis](#)

| Audit                  | User                              | Time (GMT)           |
|------------------------|-----------------------------------|----------------------|
| User entered 'Yes (Y)' | Kathy Stephens (b) (4)<br>(b) (4) | 26 Aug 2020 17:42:51 |



US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 09:35:30**

[Indication](#)

| Audit                 | User                              | Time (GMT)           |
|-----------------------|-----------------------------------|----------------------|
| User entered 'health' | Kathy Stephens (b) (4)<br>(b) (4) | 26 Aug 2020 17:42:51 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 09:35:30**

[Dose per administration](#)

| Audit               | User                              | Time (GMT)           |
|---------------------|-----------------------------------|----------------------|
| User entered '5000' | Kathy Stephens (b) (4)<br>(b) (4) | 26 Aug 2020 17:42:51 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 09:35:30**

[Dose unit](#)

| Audit                  | User                              | Time (GMT)           |
|------------------------|-----------------------------------|----------------------|
| User entered 'IU (IU)' | Kathy Stephens (b) (4)<br>(b) (4) | 26 Aug 2020 17:42:51 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 09:35:30**

If dose unit is Other, specify

| Audit               | User                              | Time (GMT)           |
|---------------------|-----------------------------------|----------------------|
| User entered empty. | Kathy Stephens (b) (4)<br>(b) (4) | 26 Aug 2020 17:42:51 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 09:35:30**

[Frequency](#)

| Audit                          | User                              | Time (GMT)           |
|--------------------------------|-----------------------------------|----------------------|
| User entered 'once daily (QD)' | Kathy Stephens (b) (4)<br>(b) (4) | 26 Aug 2020 17:42:51 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 09:35:30**

[If frequency is Other, specify](#)

| Audit               | User                              | Time (GMT)           |
|---------------------|-----------------------------------|----------------------|
| User entered empty. | Kathy Stephens (b) (4)<br>(b) (4) | 26 Aug 2020 17:42:51 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 09:35:30**

[Route of administration](#)

| Audit                      | User                              | Time (GMT)           |
|----------------------------|-----------------------------------|----------------------|
| User entered 'Oral (ORAL)' | Kathy Stephens (b) (4)<br>(b) (4) | 26 Aug 2020 17:42:51 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 09:35:30**

If route of administration is Other, specify

| Audit               | User                              | Time (GMT)           |
|---------------------|-----------------------------------|----------------------|
| User entered empty. | Kathy Stephens (b) (4)<br>(b) (4) | 26 Aug 2020 17:42:51 |



US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 09:35:30**

[Start date \(dd MMM yyyy\)](#)

| Audit               | User                              | Time (GMT)           |
|---------------------|-----------------------------------|----------------------|
| User entered empty. | Kathy Stephens (b) (4)<br>(b) (4) | 26 Aug 2020 17:42:51 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 09:35:30**

[Start date completely unknown](#)

| Audit            | User                              | Time (GMT)           |
|------------------|-----------------------------------|----------------------|
| User entered '1' | Kathy Stephens (b) (4)<br>(b) (4) | 26 Aug 2020 17:42:51 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 09:35:30**

[Ongoing?](#)

| Audit                  | User                              | Time (GMT)           |
|------------------------|-----------------------------------|----------------------|
| User entered 'Yes (Y)' | Kathy Stephens (b) (4)<br>(b) (4) | 26 Aug 2020 17:42:51 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 09:35:30**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit               | User                              | Time (GMT)           |
|---------------------|-----------------------------------|----------------------|
| User entered empty. | Kathy Stephens (b) (4)<br>(b) (4) | 26 Aug 2020 17:42:51 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 09:35:30**

[Was this medication taken for solicited event?](#)

| Audit                 | User                              | Time (GMT)           |
|-----------------------|-----------------------------------|----------------------|
| User entered 'No (N)' | Kathy Stephens (b) (4)<br>(b) (4) | 26 Aug 2020 17:42:51 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 09:35:30**

[Separate Dosage Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 26 Aug 2020 17:42:51 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 09:35:30**

[Interval Dosage Unit Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 26 Aug 2020 17:42:51 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 09:35:30**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User   | Time (GMT)           |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 26 Aug 2020 17:42:51 |



US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:35:30

[Name of Medication](#)

| Audit                                                                                                                                                                                                                                                              | User                   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------|----------------------|
| User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: OTHER PLAIN VITAMIN PREPARATIONS, ATC: OTHER PLAIN VITAMIN PREPARATIONS, PRODUCT: VITAMIN E NOS, PRODUCTSYNONYM: VITAMIN E [VITAMIN E NOS] - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)   | 27 Aug 2020 17:54:08 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.                                                                                                                                                          | Coder Import (b) (4)   | 27 Aug 2020 17:54:08 |
| Data point term sent to Coder                                                                                                                                                                                                                                      | System                 | 26 Aug 2020 17:44:27 |
| User entered 'Vitamin E'                                                                                                                                                                                                                                           | Kathy Stephens (b) (4) | 26 Aug 2020 17:44:05 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 09:35:30**

[Prophylaxis](#)

| Audit                  | User                              | Time (GMT)           |
|------------------------|-----------------------------------|----------------------|
| User entered 'Yes (Y)' | Kathy Stephens (b) (4)<br>(b) (4) | 26 Aug 2020 17:44:05 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 09:35:30**

[Indication](#)

| Audit                 | User                              | Time (GMT)           |
|-----------------------|-----------------------------------|----------------------|
| User entered 'health' | Kathy Stephens (b) (4)<br>(b) (4) | 26 Aug 2020 17:44:05 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 09:35:30**

[Dose per administration](#)

| Audit              | User                              | Time (GMT)           |
|--------------------|-----------------------------------|----------------------|
| User entered '400' | Kathy Stephens (b) (4)<br>(b) (4) | 26 Aug 2020 17:44:05 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 09:35:30**

[Dose unit](#)

| Audit                  | User                              | Time (GMT)           |
|------------------------|-----------------------------------|----------------------|
| User entered 'IU (IU)' | Kathy Stephens (b) (4)<br>(b) (4) | 26 Aug 2020 17:44:05 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 09:35:30**

If dose unit is Other, specify

| Audit               | User                              | Time (GMT)           |
|---------------------|-----------------------------------|----------------------|
| User entered empty. | Kathy Stephens (b) (4)<br>(b) (4) | 26 Aug 2020 17:44:05 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 09:35:30**

[Frequency](#)

| Audit                          | User                              | Time (GMT)           |
|--------------------------------|-----------------------------------|----------------------|
| User entered 'once daily (QD)' | Kathy Stephens (b) (4)<br>(b) (4) | 26 Aug 2020 17:44:05 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 09:35:30**

[If frequency is Other, specify](#)

| Audit               | User                              | Time (GMT)           |
|---------------------|-----------------------------------|----------------------|
| User entered empty. | Kathy Stephens (b) (4)<br>(b) (4) | 26 Aug 2020 17:44:05 |



US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 09:35:30**

[Route of administration](#)

| Audit                      | User                              | Time (GMT)           |
|----------------------------|-----------------------------------|----------------------|
| User entered 'Oral (ORAL)' | Kathy Stephens (b) (4)<br>(b) (4) | 26 Aug 2020 17:44:05 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 09:35:30**

If route of administration is Other, specify

| Audit               | User                              | Time (GMT)           |
|---------------------|-----------------------------------|----------------------|
| User entered empty. | Kathy Stephens (b) (4)<br>(b) (4) | 26 Aug 2020 17:44:05 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 09:35:30**

[Start date \(dd MMM yyyy\)](#)

| Audit               | User                              | Time (GMT)           |
|---------------------|-----------------------------------|----------------------|
| User entered empty. | Kathy Stephens (b) (4)<br>(b) (4) | 26 Aug 2020 17:44:05 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 09:35:30**

[Start date completely unknown](#)

| Audit            | User                              | Time (GMT)           |
|------------------|-----------------------------------|----------------------|
| User entered '1' | Kathy Stephens (b) (4)<br>(b) (4) | 26 Aug 2020 17:44:05 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 09:35:30**

[Ongoing?](#)

| Audit                  | User                              | Time (GMT)           |
|------------------------|-----------------------------------|----------------------|
| User entered 'Yes (Y)' | Kathy Stephens (b) (4)<br>(b) (4) | 26 Aug 2020 17:44:05 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 09:35:30**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit               | User                              | Time (GMT)           |
|---------------------|-----------------------------------|----------------------|
| User entered empty. | Kathy Stephens (b) (4)<br>(b) (4) | 26 Aug 2020 17:44:05 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 09:35:30**

[Was this medication taken for solicited event?](#)

| Audit                 | User                              | Time (GMT)           |
|-----------------------|-----------------------------------|----------------------|
| User entered 'No (N)' | Kathy Stephens (b) (4)<br>(b) (4) | 26 Aug 2020 17:44:05 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 09:35:30**

[Separate Dosage Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 26 Aug 2020 17:44:05 |



US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 09:35:30**

[Interval Dosage Unit Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 26 Aug 2020 17:44:05 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 09:35:30**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User   | Time (GMT)           |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 26 Aug 2020 17:44:05 |

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:35:30

[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-STERIODS, ATC: OTHER<br>ANTIINFLAMMATORY AND ANTIRHEUMATIC<br>AGENTS, NON-STERIODS, PRODUCT:<br>CHONDROITIN;GLUCOSAMINE - version<br>WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4)   | 29 Aug 2020 14:56:44 |
| 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 Aug 2020 14:56:44 |
| Data point term sent to Coder                                                                                                                                                                                                                                                                                                                 | System                            | 26 Aug 2020 17:45:30 |
| User entered 'Glucosamine Chondroitin'                                                                                                                                                                                                                                                                                                        | Kathy Stephens (b) (4)<br>(b) (4) | 26 Aug 2020 17:45:02 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 09:35:30**

[Prophylaxis](#)

| Audit                  | User                              | Time (GMT)           |
|------------------------|-----------------------------------|----------------------|
| User entered 'Yes (Y)' | Kathy Stephens (b) (4)<br>(b) (4) | 26 Aug 2020 17:45:02 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 09:35:30**

[Indication](#)

| Audit                 | User                              | Time (GMT)           |
|-----------------------|-----------------------------------|----------------------|
| User entered 'health' | Kathy Stephens (b) (4)<br>(b) (4) | 26 Aug 2020 17:45:02 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 09:35:30**

[Dose per administration](#)

| Audit              | User                              | Time (GMT)           |
|--------------------|-----------------------------------|----------------------|
| User entered '500' | Kathy Stephens (b) (4)<br>(b) (4) | 26 Aug 2020 17:45:02 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 09:35:30**

[Dose unit](#)

| Audit                  | User                              | Time (GMT)           |
|------------------------|-----------------------------------|----------------------|
| User entered 'mg (mg)' | Kathy Stephens (b) (4)<br>(b) (4) | 26 Aug 2020 17:45:02 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 09:35:30**

If dose unit is Other, specify

| Audit               | User                              | Time (GMT)           |
|---------------------|-----------------------------------|----------------------|
| User entered empty. | Kathy Stephens (b) (4)<br>(b) (4) | 26 Aug 2020 17:45:02 |



US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 09:35:30**

[Frequency](#)

| Audit                            | User                              | Time (GMT)           |
|----------------------------------|-----------------------------------|----------------------|
| User entered 'twice daily (BID)' | Kathy Stephens (b) (4)<br>(b) (4) | 26 Aug 2020 17:45:02 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 09:35:30**

[If frequency is Other, specify](#)

| Audit               | User                              | Time (GMT)           |
|---------------------|-----------------------------------|----------------------|
| User entered empty. | Kathy Stephens (b) (4)<br>(b) (4) | 26 Aug 2020 17:45:02 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 09:35:30**

[Route of administration](#)

| Audit                      | User                              | Time (GMT)           |
|----------------------------|-----------------------------------|----------------------|
| User entered 'Oral (ORAL)' | Kathy Stephens (b) (4)<br>(b) (4) | 26 Aug 2020 17:45:02 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 09:35:30**

If route of administration is Other, specify

| Audit               | User                              | Time (GMT)           |
|---------------------|-----------------------------------|----------------------|
| User entered empty. | Kathy Stephens (b) (4)<br>(b) (4) | 26 Aug 2020 17:45:02 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 09:35:30**

[Start date \(dd MMM yyyy\)](#)

| Audit               | User                              | Time (GMT)           |
|---------------------|-----------------------------------|----------------------|
| User entered empty. | Kathy Stephens (b) (4)<br>(b) (4) | 26 Aug 2020 17:45:02 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 09:35:30**

[Start date completely unknown](#)

| Audit            | User                              | Time (GMT)           |
|------------------|-----------------------------------|----------------------|
| User entered '1' | Kathy Stephens (b) (4)<br>(b) (4) | 26 Aug 2020 17:45:02 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 09:35:30**

[Ongoing?](#)

| Audit                  | User                              | Time (GMT)           |
|------------------------|-----------------------------------|----------------------|
| User entered 'Yes (Y)' | Kathy Stephens (b) (4)<br>(b) (4) | 26 Aug 2020 17:45:02 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 09:35:30**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit               | User                              | Time (GMT)           |
|---------------------|-----------------------------------|----------------------|
| User entered empty. | Kathy Stephens (b) (4)<br>(b) (4) | 26 Aug 2020 17:45:02 |



US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 09:35:30**

[Was this medication taken for solicited event?](#)

| Audit                 | User                              | Time (GMT)           |
|-----------------------|-----------------------------------|----------------------|
| User entered 'No (N)' | Kathy Stephens (b) (4)<br>(b) (4) | 26 Aug 2020 17:45:02 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 09:35:30**

[Separate Dosage Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '2' | System | 26 Aug 2020 17:45:02 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 09:35:30**

[Interval Dosage Unit Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 26 Aug 2020 17:45:02 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 09:35:30**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User   | Time (GMT)           |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 26 Aug 2020 17:45:02 |

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:35:30

[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)   | 11 Oct 2020 05:09:16 |
| 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)   | 11 Oct 2020 05:09:16 |
| Data point term sent to Coder                                                                                                                                                               | System                            | 10 Oct 2020 22:44:59 |
| User entered 'flu ad'                                                                                                                                                                       | Kathy Stephens (b) (4)<br>(b) (4) | 10 Oct 2020 22:44:35 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 09:35:30**

[Prophylaxis](#)

| Audit                  | User                              | Time (GMT)           |
|------------------------|-----------------------------------|----------------------|
| User entered 'Yes (Y)' | Kathy Stephens (b) (4)<br>(b) (4) | 10 Oct 2020 22:44:35 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 09:35:30**

[Indication](#)

| Audit                             | User                              | Time (GMT)           |
|-----------------------------------|-----------------------------------|----------------------|
| User entered 'annual flu vaccine' | Kathy Stephens (b) (4)<br>(b) (4) | 10 Oct 2020 22:44:35 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 09:35:30**

[Dose per administration](#)

| Audit              | User                              | Time (GMT)           |
|--------------------|-----------------------------------|----------------------|
| User entered '0.5' | Kathy Stephens (b) (4)<br>(b) (4) | 10 Oct 2020 22:44:35 |



US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 09:35:30**

[Dose unit](#)

| Audit                  | User                              | Time (GMT)           |
|------------------------|-----------------------------------|----------------------|
| User entered 'mg (mg)' | Kathy Stephens (b) (4)<br>(b) (4) | 10 Oct 2020 22:44:35 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 09:35:30**

If dose unit is Other, specify

| Audit               | User                              | Time (GMT)           |
|---------------------|-----------------------------------|----------------------|
| User entered empty. | Kathy Stephens (b) (4)<br>(b) (4) | 10 Oct 2020 22:44:35 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 09:35:30**

[Frequency](#)

| Audit                      | User                              | Time (GMT)           |
|----------------------------|-----------------------------------|----------------------|
| User entered 'once (ONCE)' | Kathy Stephens (b) (4)<br>(b) (4) | 10 Oct 2020 22:44:35 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 09:35:30**

[If frequency is Other, specify](#)

| Audit               | User                              | Time (GMT)           |
|---------------------|-----------------------------------|----------------------|
| User entered empty. | Kathy Stephens (b) (4)<br>(b) (4) | 10 Oct 2020 22:44:35 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 09:35:30**

[Route of administration](#)

| Audit                                        | User                              | Time (GMT)           |
|----------------------------------------------|-----------------------------------|----------------------|
| User entered 'Intramuscular (INTRAMUSCULAR)' | Kathy Stephens (b) (4)<br>(b) (4) | 10 Oct 2020 22:44:35 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 09:35:30**

If route of administration is Other, specify

| Audit               | User                              | Time (GMT)           |
|---------------------|-----------------------------------|----------------------|
| User entered empty. | Kathy Stephens (b) (4)<br>(b) (4) | 10 Oct 2020 22:44:35 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 09:35:30**

[Start date \(dd MMM yyyy\)](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| User entered '7 Oct 2020' | Kathy Stephens (b) (4)<br>(b) (4) | 10 Oct 2020 22:44:35 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 09:35:30**

[Start date completely unknown](#)

| Audit            | User                              | Time (GMT)           |
|------------------|-----------------------------------|----------------------|
| User entered '0' | Kathy Stephens (b) (4)<br>(b) (4) | 10 Oct 2020 22:44:35 |



US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 09:35:30**

[Ongoing?](#)

| Audit                 | User                              | Time (GMT)           |
|-----------------------|-----------------------------------|----------------------|
| User entered 'No (N)' | Kathy Stephens (b) (4)<br>(b) (4) | 10 Oct 2020 22:44:35 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 09:35:30**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| User entered '7 Oct 2020' | Kathy Stephens (b) (4)<br>(b) (4) | 10 Oct 2020 22:44:35 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 09:35:30**

[Was this medication taken for solicited event?](#)

| Audit                 | User                              | Time (GMT)           |
|-----------------------|-----------------------------------|----------------------|
| User entered 'No (N)' | Kathy Stephens (b) (4)<br>(b) (4) | 10 Oct 2020 22:44:35 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 09:35:30**

[Separate Dosage Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 10 Oct 2020 22:44:35 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 09:35:30**

[Interval Dosage Unit Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 10 Oct 2020 22:44:35 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 09:35:30**

[Interval Dosage Definition \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 10 Oct 2020 22:44:35 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 09:35:30**

[Name of Medication](#)

| Audit                                                                                                                                                                                                                                   | User                   | Time (GMT)           |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------|----------------------|
| User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: DIRECT FACTOR XA INHIBITORS, PRODUCT: APIXABAN, PRODUCTSYNONYM: ELIQUIS - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)   | 17 Nov 2020 01:42:55 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.                                                                                                                               | Coder Import (b) (4)   | 17 Nov 2020 01:42:55 |
| Data point term sent to Coder                                                                                                                                                                                                           | System                 | 17 Nov 2020 01:42:28 |
| User entered 'eliquis'                                                                                                                                                                                                                  | Kathy Stephens (b) (4) | 17 Nov 2020 01:42:01 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 09:35:30**

[Prophylaxis](#)

| Audit                  | User                              | Time (GMT)           |
|------------------------|-----------------------------------|----------------------|
| User entered 'Yes (Y)' | Kathy Stephens (b) (4)<br>(b) (4) | 17 Nov 2020 01:42:01 |



US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 09:35:30**

[Indication](#)

| Audit                                        | User                              | Time (GMT)           |
|----------------------------------------------|-----------------------------------|----------------------|
| User entered 'Post surgical DVT prophylaxis' | Kathy Stephens (b) (4)<br>(b) (4) | 17 Nov 2020 01:42:01 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 09:35:30**

[Dose per administration](#)

| Audit              | User                              | Time (GMT)           |
|--------------------|-----------------------------------|----------------------|
| User entered '2.5' | Kathy Stephens (b) (4)<br>(b) (4) | 17 Nov 2020 01:42:01 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 09:35:30**

[Dose unit](#)

| Audit                  | User                              | Time (GMT)           |
|------------------------|-----------------------------------|----------------------|
| User entered 'mg (mg)' | Kathy Stephens (b) (4)<br>(b) (4) | 17 Nov 2020 01:42:01 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 09:35:30**

If dose unit is Other, specify

| Audit               | User                              | Time (GMT)           |
|---------------------|-----------------------------------|----------------------|
| User entered empty. | Kathy Stephens (b) (4)<br>(b) (4) | 17 Nov 2020 01:42:01 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 09:35:30**

[Frequency](#)

| Audit                            | User                              | Time (GMT)           |
|----------------------------------|-----------------------------------|----------------------|
| User entered 'twice daily (BID)' | Kathy Stephens (b) (4)<br>(b) (4) | 17 Nov 2020 01:42:01 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 09:35:30**

[If frequency is Other, specify](#)

| Audit               | User                              | Time (GMT)           |
|---------------------|-----------------------------------|----------------------|
| User entered empty. | Kathy Stephens (b) (4)<br>(b) (4) | 17 Nov 2020 01:42:01 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 09:35:30**

[Route of administration](#)

| Audit                      | User                              | Time (GMT)           |
|----------------------------|-----------------------------------|----------------------|
| User entered 'Oral (ORAL)' | Kathy Stephens (b) (4)<br>(b) (4) | 17 Nov 2020 01:42:01 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 09:35:30**

If route of administration is Other, specify

| Audit               | User                              | Time (GMT)           |
|---------------------|-----------------------------------|----------------------|
| User entered empty. | Kathy Stephens (b) (4)<br>(b) (4) | 17 Nov 2020 01:42:01 |



US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 09:35:30**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                              | Time (GMT)           |
|----------------------------|-----------------------------------|----------------------|
| User entered '01 Nov 2020' | Kathy Stephens (b) (4)<br>(b) (4) | 17 Nov 2020 01:42:01 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 09:35:30**

[Start date completely unknown](#)

| Audit            | User                              | Time (GMT)           |
|------------------|-----------------------------------|----------------------|
| User entered '0' | Kathy Stephens (b) (4)<br>(b) (4) | 17 Nov 2020 01:42:01 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 09:35:30**

[Ongoing?](#)

| Audit                  | User                              | Time (GMT)           |
|------------------------|-----------------------------------|----------------------|
| User entered 'Yes (Y)' | Kathy Stephens (b) (4)<br>(b) (4) | 17 Nov 2020 01:42:01 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 09:35:30**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit               | User                              | Time (GMT)           |
|---------------------|-----------------------------------|----------------------|
| User entered empty. | Kathy Stephens (b) (4)<br>(b) (4) | 17 Nov 2020 01:42:01 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 09:35:30**

[Was this medication taken for solicited event?](#)

| Audit                 | User                              | Time (GMT)           |
|-----------------------|-----------------------------------|----------------------|
| User entered 'No (N)' | Kathy Stephens (b) (4)<br>(b) (4) | 17 Nov 2020 01:42:01 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 09:35:30**

[Separate Dosage Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '2' | System | 17 Nov 2020 01:42:01 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 09:35:30**

[Interval Dosage Unit Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 17 Nov 2020 01:42:01 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 09:35:30**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User   | Time (GMT)           |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 17 Nov 2020 01:42:01 |



US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 09:35:30**

[Name of Medication](#)

| Audit                                                                                                                                                                                                                                                                                                                           | User                              | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------|----------------------|
| User coded data point as ATC:<br>MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE<br>RELAXANTS, ATC: MUSCLE RELAXANTS,<br>CENTRALLY ACTING AGENTS, ATC: OTHER<br>CENTRALLY ACTING AGENTS, PRODUCT:<br>CYCLOBENZAPRINE HYDROCHLORIDE,<br>PRODUCTSYNONYM: FLEXERIL<br>[CYCLOBENZAPRINE HYDROCHLORIDE] -<br>version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4)   | 17 Nov 2020 02:22:50 |
| 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)   | 17 Nov 2020 02:22:50 |
| Data point term sent to Coder                                                                                                                                                                                                                                                                                                   | System                            | 17 Nov 2020 01:43:28 |
| User entered 'flexeril'                                                                                                                                                                                                                                                                                                         | Kathy Stephens (b) (4)<br>(b) (4) | 17 Nov 2020 01:43:11 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 09:35:30**

[Prophylaxis](#)

| Audit                 | User                              | Time (GMT)           |
|-----------------------|-----------------------------------|----------------------|
| User entered 'No (N)' | Kathy Stephens (b) (4)<br>(b) (4) | 17 Nov 2020 01:43:11 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 09:35:30**

[Indication](#)

| Audit                                      | User                              | Time (GMT)           |
|--------------------------------------------|-----------------------------------|----------------------|
| User entered 'post surgical muscle spasms' | Kathy Stephens (b) (4)<br>(b) (4) | 17 Nov 2020 01:43:11 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 09:35:30**

[Dose per administration](#)

| Audit            | User                              | Time (GMT)           |
|------------------|-----------------------------------|----------------------|
| User entered '5' | Kathy Stephens (b) (4)<br>(b) (4) | 17 Nov 2020 01:43:11 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 09:35:30**

[Dose unit](#)

| Audit                  | User                              | Time (GMT)           |
|------------------------|-----------------------------------|----------------------|
| User entered 'mg (mg)' | Kathy Stephens (b) (4)<br>(b) (4) | 17 Nov 2020 01:43:11 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 09:35:30**

If dose unit is Other, specify

| Audit               | User                              | Time (GMT)           |
|---------------------|-----------------------------------|----------------------|
| User entered empty. | Kathy Stephens (b) (4)<br>(b) (4) | 17 Nov 2020 01:43:11 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 09:35:30**

[Frequency](#)

| Audit                          | User                              | Time (GMT)           |
|--------------------------------|-----------------------------------|----------------------|
| User entered 'as needed (PRN)' | Kathy Stephens (b) (4)<br>(b) (4) | 17 Nov 2020 01:43:11 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 09:35:30**

[If frequency is Other, specify](#)

| Audit               | User                              | Time (GMT)           |
|---------------------|-----------------------------------|----------------------|
| User entered empty. | Kathy Stephens (b) (4)<br>(b) (4) | 17 Nov 2020 01:43:11 |



US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 09:35:30**

[Route of administration](#)

| Audit                      | User                              | Time (GMT)           |
|----------------------------|-----------------------------------|----------------------|
| User entered 'Oral (ORAL)' | Kathy Stephens (b) (4)<br>(b) (4) | 17 Nov 2020 01:43:11 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 09:35:30**

If route of administration is Other, specify

| Audit               | User                              | Time (GMT)           |
|---------------------|-----------------------------------|----------------------|
| User entered empty. | Kathy Stephens (b) (4)<br>(b) (4) | 17 Nov 2020 01:43:11 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 09:35:30**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                              | Time (GMT)           |
|----------------------------|-----------------------------------|----------------------|
| User entered '01 Nov 2020' | Kathy Stephens (b) (4)<br>(b) (4) | 17 Nov 2020 01:43:11 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 09:35:30**

[Start date completely unknown](#)

| Audit            | User                              | Time (GMT)           |
|------------------|-----------------------------------|----------------------|
| User entered '0' | Kathy Stephens (b) (4)<br>(b) (4) | 17 Nov 2020 01:43:11 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 09:35:30**

[Ongoing?](#)

| Audit                  | User                              | Time (GMT)           |
|------------------------|-----------------------------------|----------------------|
| User entered 'Yes (Y)' | Kathy Stephens (b) (4)<br>(b) (4) | 17 Nov 2020 01:43:11 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 09:35:30**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit               | User                              | Time (GMT)           |
|---------------------|-----------------------------------|----------------------|
| User entered empty. | Kathy Stephens (b) (4)<br>(b) (4) | 17 Nov 2020 01:43:11 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 09:35:30**

[Was this medication taken for solicited event?](#)

| Audit                 | User                              | Time (GMT)           |
|-----------------------|-----------------------------------|----------------------|
| User entered 'No (N)' | Kathy Stephens (b) (4)<br>(b) (4) | 17 Nov 2020 01:43:11 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 09:35:30**

[Separate Dosage Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 17 Nov 2020 01:43:11 |



US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 09:35:30**

[Interval Dosage Unit Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 17 Nov 2020 01:43:11 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 09:35:30**

[Interval Dosage Definition \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 17 Nov 2020 01:43:11 |

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:35:30

[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: SOFTENERS, EMOLLIENTS, PRODUCT: DOCUSATE SODIUM, PRODUCTSYNONYM: COLACE - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4)   | 17 Nov 2020 02:12:50 |
| 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)   | 17 Nov 2020 02:12:50 |
| Data point term sent to Coder                                                                                                                                                                                                              | System                            | 17 Nov 2020 01:44:28 |
| User entered 'Colace'                                                                                                                                                                                                                      | Kathy Stephens (b) (4)<br>(b) (4) | 17 Nov 2020 01:43:57 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 09:35:30**

[Prophylaxis](#)

| Audit                  | User                              | Time (GMT)           |
|------------------------|-----------------------------------|----------------------|
| User entered 'Yes (Y)' | Kathy Stephens (b) (4)<br>(b) (4) | 17 Nov 2020 01:43:57 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 09:35:30**

[Indication](#)

| Audit                                     | User                              | Time (GMT)           |
|-------------------------------------------|-----------------------------------|----------------------|
| User entered 'Post surgical constipation' | Kathy Stephens (b) (4)<br>(b) (4) | 17 Nov 2020 01:43:57 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 09:35:30**

[Dose per administration](#)

| Audit              | User                              | Time (GMT)           |
|--------------------|-----------------------------------|----------------------|
| User entered '100' | Kathy Stephens (b) (4)<br>(b) (4) | 17 Nov 2020 01:43:57 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 09:35:30**

[Dose unit](#)

| Audit                  | User                              | Time (GMT)           |
|------------------------|-----------------------------------|----------------------|
| User entered 'mg (mg)' | Kathy Stephens (b) (4)<br>(b) (4) | 17 Nov 2020 01:43:57 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 09:35:30**

If dose unit is Other, specify

| Audit               | User                              | Time (GMT)           |
|---------------------|-----------------------------------|----------------------|
| User entered empty. | Kathy Stephens (b) (4)<br>(b) (4) | 17 Nov 2020 01:43:57 |



US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 09:35:30**

[Frequency](#)

| Audit                          | User                              | Time (GMT)           |
|--------------------------------|-----------------------------------|----------------------|
| User entered 'as needed (PRN)' | Kathy Stephens (b) (4)<br>(b) (4) | 17 Nov 2020 01:43:57 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 09:35:30**

[If frequency is Other, specify](#)

| Audit               | User                              | Time (GMT)           |
|---------------------|-----------------------------------|----------------------|
| User entered empty. | Kathy Stephens (b) (4)<br>(b) (4) | 17 Nov 2020 01:43:57 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 09:35:30**

[Route of administration](#)

| Audit                      | User                              | Time (GMT)           |
|----------------------------|-----------------------------------|----------------------|
| User entered 'Oral (ORAL)' | Kathy Stephens (b) (4)<br>(b) (4) | 17 Nov 2020 01:43:57 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 09:35:30**

If route of administration is Other, specify

| Audit               | User                              | Time (GMT)           |
|---------------------|-----------------------------------|----------------------|
| User entered empty. | Kathy Stephens (b) (4)<br>(b) (4) | 17 Nov 2020 01:43:57 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 09:35:30**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                              | Time (GMT)           |
|----------------------------|-----------------------------------|----------------------|
| User entered '01 Nov 2020' | Kathy Stephens (b) (4)<br>(b) (4) | 17 Nov 2020 01:43:57 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 09:35:30**

[Start date completely unknown](#)

| Audit            | User                              | Time (GMT)           |
|------------------|-----------------------------------|----------------------|
| User entered '0' | Kathy Stephens (b) (4)<br>(b) (4) | 17 Nov 2020 01:43:57 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 09:35:30**

[Ongoing?](#)

| Audit                  | User                              | Time (GMT)           |
|------------------------|-----------------------------------|----------------------|
| User entered 'Yes (Y)' | Kathy Stephens (b) (4)<br>(b) (4) | 17 Nov 2020 01:43:57 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 09:35:30**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit               | User                              | Time (GMT)           |
|---------------------|-----------------------------------|----------------------|
| User entered empty. | Kathy Stephens (b) (4)<br>(b) (4) | 17 Nov 2020 01:43:57 |



US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 09:35:30**

[Was this medication taken for solicited event?](#)

| Audit                 | User                              | Time (GMT)           |
|-----------------------|-----------------------------------|----------------------|
| User entered 'No (N)' | Kathy Stephens (b) (4)<br>(b) (4) | 17 Nov 2020 01:43:57 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 09:35:30**

[Separate Dosage Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 17 Nov 2020 01:43:57 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 09:35:30**

[Interval Dosage Unit Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 17 Nov 2020 01:43:57 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 09:35:30**

[Interval Dosage Definition \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 17 Nov 2020 01:43:57 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 09:35:30**

[Name of Medication](#)

| Audit                                                                                                                                                                                                                                                                     | User                              | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------|----------------------|
| User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON, PRODUCTSYNONYM: ZOFRAN [ONDANSETRON] - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4)   | 17 Nov 2020 03:25:51 |
| 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)   | 17 Nov 2020 03:25:51 |
| Data point term sent to Coder                                                                                                                                                                                                                                             | System                            | 17 Nov 2020 01:45:29 |
| User entered 'Zofran'                                                                                                                                                                                                                                                     | Kathy Stephens (b) (4)<br>(b) (4) | 17 Nov 2020 01:45:01 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 09:35:30**

[Prophylaxis](#)

| Audit                  | User                              | Time (GMT)           |
|------------------------|-----------------------------------|----------------------|
| User entered 'Yes (Y)' | Kathy Stephens (b) (4)<br>(b) (4) | 17 Nov 2020 01:45:01 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 09:35:30**

[Indication](#)

| Audit                               | User                              | Time (GMT)           |
|-------------------------------------|-----------------------------------|----------------------|
| User entered 'post surgical nausea' | Kathy Stephens (b) (4)<br>(b) (4) | 17 Nov 2020 01:45:01 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 09:35:30**

[Dose per administration](#)

| Audit            | User                              | Time (GMT)           |
|------------------|-----------------------------------|----------------------|
| User entered '4' | Kathy Stephens (b) (4)<br>(b) (4) | 17 Nov 2020 01:45:01 |



US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 09:35:30**

[Dose unit](#)

| Audit                  | User                              | Time (GMT)           |
|------------------------|-----------------------------------|----------------------|
| User entered 'mg (mg)' | Kathy Stephens (b) (4)<br>(b) (4) | 17 Nov 2020 01:45:01 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 09:35:30**

If dose unit is Other, specify

| Audit               | User                              | Time (GMT)           |
|---------------------|-----------------------------------|----------------------|
| User entered empty. | Kathy Stephens (b) (4)<br>(b) (4) | 17 Nov 2020 01:45:01 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 09:35:30**

[Frequency](#)

| Audit                          | User                              | Time (GMT)           |
|--------------------------------|-----------------------------------|----------------------|
| User entered 'as needed (PRN)' | Kathy Stephens (b) (4)<br>(b) (4) | 17 Nov 2020 01:45:01 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 09:35:30**

[If frequency is Other, specify](#)

| Audit               | User                              | Time (GMT)           |
|---------------------|-----------------------------------|----------------------|
| User entered empty. | Kathy Stephens (b) (4)<br>(b) (4) | 17 Nov 2020 01:45:01 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 09:35:30**

[Route of administration](#)

| Audit                      | User                              | Time (GMT)           |
|----------------------------|-----------------------------------|----------------------|
| User entered 'Oral (ORAL)' | Kathy Stephens (b) (4)<br>(b) (4) | 17 Nov 2020 01:45:01 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 09:35:30**

If route of administration is Other, specify

| Audit               | User                              | Time (GMT)           |
|---------------------|-----------------------------------|----------------------|
| User entered empty. | Kathy Stephens (b) (4)<br>(b) (4) | 17 Nov 2020 01:45:01 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 09:35:30**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                              | Time (GMT)           |
|----------------------------|-----------------------------------|----------------------|
| User entered '01 Nov 2020' | Kathy Stephens (b) (4)<br>(b) (4) | 17 Nov 2020 01:45:01 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 09:35:30**

[Start date completely unknown](#)

| Audit            | User                              | Time (GMT)           |
|------------------|-----------------------------------|----------------------|
| User entered '0' | Kathy Stephens (b) (4)<br>(b) (4) | 17 Nov 2020 01:45:01 |



US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 09:35:30**

[Ongoing?](#)

| Audit                  | User                              | Time (GMT)           |
|------------------------|-----------------------------------|----------------------|
| User entered 'Yes (Y)' | Kathy Stephens (b) (4)<br>(b) (4) | 17 Nov 2020 01:45:01 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 09:35:30**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit               | User                              | Time (GMT)           |
|---------------------|-----------------------------------|----------------------|
| User entered empty. | Kathy Stephens (b) (4)<br>(b) (4) | 17 Nov 2020 01:45:01 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 09:35:30**

[Was this medication taken for solicited event?](#)

| Audit                 | User                              | Time (GMT)           |
|-----------------------|-----------------------------------|----------------------|
| User entered 'No (N)' | Kathy Stephens (b) (4)<br>(b) (4) | 17 Nov 2020 01:45:01 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 09:35:30**

[Separate Dosage Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 17 Nov 2020 01:45:01 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 09:35:30**

[Interval Dosage Unit Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 17 Nov 2020 01:45:01 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 09:35:30**

[Interval Dosage Definition \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 17 Nov 2020 01:45:01 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 26 Nov 2020 09:35:30**

[Name of Medication](#)

| Audit                                                                                                                                                                                                                                                                                  | User                              | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------|----------------------|
| User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: OXYCODONE HYDROCHLORIDE;PARACETAMOL, PRODUCTSYNONYM: PERCOCET [OXYCODONE HYDROCHLORIDE;PARACETAMOL] - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4)   | 17 Nov 2020 07:04:53 |
| 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)   | 17 Nov 2020 07:04:53 |
| Data point term sent to Coder                                                                                                                                                                                                                                                          | System                            | 17 Nov 2020 01:46:29 |
| User entered 'Percoset'                                                                                                                                                                                                                                                                | Kathy Stephens (b) (4)<br>(b) (4) | 17 Nov 2020 01:45:54 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 26 Nov 2020 09:35:30**

[Prophylaxis](#)

| Audit                 | User                              | Time (GMT)           |
|-----------------------|-----------------------------------|----------------------|
| User entered 'No (N)' | Kathy Stephens (b) (4)<br>(b) (4) | 17 Nov 2020 01:45:54 |



US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 26 Nov 2020 09:35:30**

[Indication](#)

| Audit                            | User                              | Time (GMT)           |
|----------------------------------|-----------------------------------|----------------------|
| User entered 'Postsurgical pain' | Kathy Stephens (b) (4)<br>(b) (4) | 17 Nov 2020 01:45:54 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 26 Nov 2020 09:35:30**

[Dose per administration](#)

| Audit                  | User                              | Time (GMT)           |
|------------------------|-----------------------------------|----------------------|
| User entered '7.5/325' | Kathy Stephens (b) (4)<br>(b) (4) | 17 Nov 2020 01:45:54 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 26 Nov 2020 09:35:30**

[Dose unit](#)

| Audit                  | User                              | Time (GMT)           |
|------------------------|-----------------------------------|----------------------|
| User entered 'mg (mg)' | Kathy Stephens (b) (4)<br>(b) (4) | 17 Nov 2020 01:45:54 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 26 Nov 2020 09:35:30**

If dose unit is Other, specify

| Audit               | User                              | Time (GMT)           |
|---------------------|-----------------------------------|----------------------|
| User entered empty. | Kathy Stephens (b) (4)<br>(b) (4) | 17 Nov 2020 01:45:54 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 26 Nov 2020 09:35:30**

[Frequency](#)

| Audit                          | User                              | Time (GMT)           |
|--------------------------------|-----------------------------------|----------------------|
| User entered 'as needed (PRN)' | Kathy Stephens (b) (4)<br>(b) (4) | 17 Nov 2020 01:45:54 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 26 Nov 2020 09:35:30**

[If frequency is Other, specify](#)

| Audit               | User                              | Time (GMT)           |
|---------------------|-----------------------------------|----------------------|
| User entered empty. | Kathy Stephens (b) (4)<br>(b) (4) | 17 Nov 2020 01:45:54 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 26 Nov 2020 09:35:30**

[Route of administration](#)

| Audit                      | User                              | Time (GMT)           |
|----------------------------|-----------------------------------|----------------------|
| User entered 'Oral (ORAL)' | Kathy Stephens (b) (4)<br>(b) (4) | 17 Nov 2020 01:45:54 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 26 Nov 2020 09:35:30**

If route of administration is Other, specify

| Audit               | User                              | Time (GMT)           |
|---------------------|-----------------------------------|----------------------|
| User entered empty. | Kathy Stephens (b) (4)<br>(b) (4) | 17 Nov 2020 01:45:54 |



US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 26 Nov 2020 09:35:30**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                              | Time (GMT)           |
|----------------------------|-----------------------------------|----------------------|
| User entered '01 Nov 2020' | Kathy Stephens (b) (4)<br>(b) (4) | 17 Nov 2020 01:45:54 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 26 Nov 2020 09:35:30**

[Start date completely unknown](#)

| Audit            | User                              | Time (GMT)           |
|------------------|-----------------------------------|----------------------|
| User entered '0' | Kathy Stephens (b) (4)<br>(b) (4) | 17 Nov 2020 01:45:54 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 26 Nov 2020 09:35:30**

[Ongoing?](#)

| Audit                  | User                              | Time (GMT)           |
|------------------------|-----------------------------------|----------------------|
| User entered 'Yes (Y)' | Kathy Stephens (b) (4)<br>(b) (4) | 17 Nov 2020 01:45:54 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 26 Nov 2020 09:35:30**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit               | User                              | Time (GMT)           |
|---------------------|-----------------------------------|----------------------|
| User entered empty. | Kathy Stephens (b) (4)<br>(b) (4) | 17 Nov 2020 01:45:54 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 26 Nov 2020 09:35:30**

[Was this medication taken for solicited event?](#)

| Audit                 | User                              | Time (GMT)           |
|-----------------------|-----------------------------------|----------------------|
| User entered 'No (N)' | Kathy Stephens (b) (4)<br>(b) (4) | 17 Nov 2020 01:45:54 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 26 Nov 2020 09:35:30**

[Separate Dosage Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 17 Nov 2020 01:45:54 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 26 Nov 2020 09:35:30**

[Interval Dosage Unit Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 17 Nov 2020 01:45:54 |

US3532063

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 26 Nov 2020 09:35:30**

[Interval Dosage Definition \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 17 Nov 2020 01:45:54 |



US3532063

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures Summary**

**Generated On: 26 Nov 2020 09:35:30**

[Were any concomitant procedures performed?](#)

| Audit                  | User                              | Time (GMT)           |
|------------------------|-----------------------------------|----------------------|
| User entered 'Yes (Y)' | Kathy Stephens (b) (4)<br>(b) (4) | 11 Nov 2020 18:50:43 |

US3532063

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (1)**

**Generated On: 26 Nov 2020 09:35:30**

[Procedure/Surgery date \(dd MMM yyyy\)](#)

| Audit                      | User                              | Time (GMT)           |
|----------------------------|-----------------------------------|----------------------|
| User entered '29 Oct 2020' | Kathy Stephens (b) (4)<br>(b) (4) | 11 Nov 2020 18:51:37 |

US3532063

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (1)**

**Generated On: 26 Nov 2020 09:35:30**

[Procedure/Surgery](#)

| Audit                                             | User                              | Time (GMT)           |
|---------------------------------------------------|-----------------------------------|----------------------|
| User entered 'Surgical repair of fractured femur' | Kathy Stephens (b) (4)<br>(b) (4) | 11 Nov 2020 18:51:37 |

US3532063

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (1)**

**Generated On: 26 Nov 2020 09:35:30**

[Indication](#)

| Audit                             | User                              | Time (GMT)           |
|-----------------------------------|-----------------------------------|----------------------|
| User entered 'Adverse Event (AE)' | Kathy Stephens (b) (4)<br>(b) (4) | 11 Nov 2020 18:51:37 |

US3532063

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (1)**

**Generated On: 26 Nov 2020 09:35:30**

[If indication is Other, specify](#)

| Audit               | User                              | Time (GMT)           |
|---------------------|-----------------------------------|----------------------|
| User entered empty. | Kathy Stephens (b) (4)<br>(b) (4) | 11 Nov 2020 18:51:37 |

US3532063

**Folder:** SAE USA-US077-2020-MRNA-1273-P301000007

**Form:** Safety Report Form

**Generated On:** 26 Nov 2020 09:35:30

[SAEID](#)

| Audit                                                 | User             | Time (GMT)           |
|-------------------------------------------------------|------------------|----------------------|
| Reviewed for Safety.                                  | (b) (4), (b) (6) | 04 Nov 2020 17:43:53 |
|                                                       |                  |                      |
| User entered<br>'USA-US077-2020-MRNA-1273-P301000007' | System           | 04 Nov 2020 17:43:27 |

US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:30

Serious

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| Reviewed for Safety.   | (b) (4), (b) (6) | 04 Nov 2020 17:43:53 |
|                        |                  |                      |
| User entered 'Yes (Y)' | System           | 04 Nov 2020 17:43:27 |

US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:30

[Death](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| Reviewed for Safety.  | (b) (4), (b) (6) | 04 Nov 2020 17:43:53 |
|                       |                  |                      |
| User entered 'No (N)' | System           | 04 Nov 2020 17:43:27 |



US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:30

[Life threatening](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| Reviewed for Safety.  | (b) (4), (b) (6) | 04 Nov 2020 17:43:53 |
|                       |                  |                      |
| User entered 'No (N)' | System           | 04 Nov 2020 17:43:27 |

US3532063

**Folder:** SAE USA-US077-2020-MRNA-1273-P301000007

**Form:** Safety Report Form

**Generated On:** 26 Nov 2020 09:35:30

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| Reviewed for Safety.   | (b) (4), (b) (6) | 04 Nov 2020 17:43:53 |
|                        |                  |                      |
| User entered 'Yes (Y)' | System           | 04 Nov 2020 17:43:27 |

US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:30

[Persistent or significant disability or incapacity](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| Reviewed for Safety.  | (b) (4), (b) (6) | 04 Nov 2020 17:43:53 |
|                       |                  |                      |
| User entered 'No (N)' | System           | 04 Nov 2020 17:43:27 |

US3532063

**Folder:** SAE USA-US077-2020-MRNA-1273-P301000007

**Form:** Safety Report Form

**Generated On:** 26 Nov 2020 09:35:30

[Congenital anomaly or birth defect](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| Reviewed for Safety.  | (b) (4), (b) (6) | 04 Nov 2020 17:43:53 |
|                       |                  |                      |
| User entered 'No (N)' | System           | 04 Nov 2020 17:43:27 |

US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:30

[Other medically important event](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| Reviewed for Safety.  | (b) (4), (b) (6) | 04 Nov 2020 17:43:53 |
|                       |                  |                      |
| User entered 'No (N)' | System           | 04 Nov 2020 17:43:27 |

US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:30

[Investigator's First Name](#)

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 04 Nov 2020 17:43:53 |
|                      |                  |                      |
| User entered 'Evan'  | System           | 04 Nov 2020 17:43:27 |

US3532063

**Folder:** SAE USA-US077-2020-MRNA-1273-P301000007

**Form:** Safety Report Form

**Generated On:** 26 Nov 2020 09:35:30

[Investigator's Last Name](#)

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| Reviewed for Safety.    | (b) (4), (b) (6) | 04 Nov 2020 17:43:53 |
|                         |                  |                      |
| User entered 'Anderson' | System           | 04 Nov 2020 17:43:27 |

US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:30

Site Address: [Street](#)

| Audit                               | User             | Time (GMT)           |
|-------------------------------------|------------------|----------------------|
| Reviewed for Safety.                | (b) (4), (b) (6) | 04 Nov 2020 17:43:53 |
|                                     |                  |                      |
| User entered '2015 Uppergate Drive' | System           | 04 Nov 2020 17:43:27 |



US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:30

Site Address: [City](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| Reviewed for Safety.   | (b) (4), (b) (6) | 04 Nov 2020 17:43:53 |
|                        |                  |                      |
| User entered 'Atlanta' | System           | 04 Nov 2020 17:43:27 |

US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:30

Site Address: [State](#)

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 04 Nov 2020 17:43:53 |
|                      |                  |                      |
| User entered 'GA'    | System           | 04 Nov 2020 17:43:27 |

US3532063

**Folder:** SAE USA-US077-2020-MRNA-1273-P301000007

**Form:** Safety Report Form

**Generated On:** 26 Nov 2020 09:35:30

[Site Address: Postal Code](#)

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 04 Nov 2020 17:43:53 |
|                      |                  |                      |
| User entered '30323' | System           | 04 Nov 2020 17:43:27 |

US3532063

**Folder:** SAE USA-US077-2020-MRNA-1273-P301000007

**Form:** Safety Report Form

**Generated On:** 26 Nov 2020 09:35:30

[Investigator Country](#)

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 17 Nov 2020 14:43:41 |
|                      |                  |                      |
| User entered 'US'    | System           | 04 Nov 2020 17:44:05 |

US3532063

**Folder:** SAE USA-US077-2020-MRNA-1273-P301000007

**Form:** Safety Report Form

**Generated On:** 26 Nov 2020 09:35:30

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '3' | System | 18 Nov 2020 13:46:43 |
| User entered '2' | System | 17 Nov 2020 14:43:50 |
| User entered '1' | System | 04 Nov 2020 17:44:05 |

US3532063

**Folder:** SAE USA-US077-2020-MRNA-1273-P301000007

**Form:** Safety Report Form

**Generated On:** 26 Nov 2020 09:35:30

[SAEID](#)

| Audit                                                 | User             | Time (GMT)           |
|-------------------------------------------------------|------------------|----------------------|
| Reviewed for Safety.                                  | (b) (4), (b) (6) | 04 Nov 2020 17:43:53 |
|                                                       |                  |                      |
| User entered<br>'USA-US077-2020-MRNA-1273-P301000007' | System           | 04 Nov 2020 17:43:27 |

US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:30

Serious

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| Reviewed for Safety.   | (b) (4), (b) (6) | 04 Nov 2020 17:43:53 |
|                        |                  |                      |
| User entered 'Yes (Y)' | System           | 04 Nov 2020 17:43:27 |

US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:30

[Death](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| Reviewed for Safety.  | (b) (4), (b) (6) | 04 Nov 2020 17:43:53 |
|                       |                  |                      |
| User entered 'No (N)' | System           | 04 Nov 2020 17:43:27 |



US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:30

[Life threatening](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| Reviewed for Safety.  | (b) (4), (b) (6) | 04 Nov 2020 17:43:53 |
|                       |                  |                      |
| User entered 'No (N)' | System           | 04 Nov 2020 17:43:27 |

US3532063

**Folder:** SAE USA-US077-2020-MRNA-1273-P301000007

**Form:** Safety Report Form

**Generated On:** 26 Nov 2020 09:35:30

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| Reviewed for Safety.   | (b) (4), (b) (6) | 04 Nov 2020 17:43:53 |
|                        |                  |                      |
| User entered 'Yes (Y)' | System           | 04 Nov 2020 17:43:27 |

US3532063

**Folder:** SAE USA-US077-2020-MRNA-1273-P301000007

**Form:** Safety Report Form

**Generated On:** 26 Nov 2020 09:35:30

[Persistent or significant disability or incapacity](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| Reviewed for Safety.  | (b) (4), (b) (6) | 04 Nov 2020 17:43:53 |
|                       |                  |                      |
| User entered 'No (N)' | System           | 04 Nov 2020 17:43:27 |

US3532063

**Folder:** SAE USA-US077-2020-MRNA-1273-P301000007

**Form:** Safety Report Form

**Generated On:** 26 Nov 2020 09:35:30

[Congenital anomaly or birth defect](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| Reviewed for Safety.  | (b) (4), (b) (6) | 04 Nov 2020 17:43:53 |
|                       |                  |                      |
| User entered 'No (N)' | System           | 04 Nov 2020 17:43:27 |

US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:30

[Other medically important event](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| Reviewed for Safety.  | (b) (4), (b) (6) | 04 Nov 2020 17:43:53 |
|                       |                  |                      |
| User entered 'No (N)' | System           | 04 Nov 2020 17:43:27 |

US3532063

**Folder:** SAE USA-US077-2020-MRNA-1273-P301000007

**Form:** Safety Report Form

**Generated On:** 26 Nov 2020 09:35:30

[Investigator's First Name](#)

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 04 Nov 2020 17:43:53 |
|                      |                  |                      |
| User entered 'Evan'  | System           | 04 Nov 2020 17:43:27 |

US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:30

[Investigator's Last Name](#)

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| Reviewed for Safety.    | (b) (4), (b) (6) | 04 Nov 2020 17:43:53 |
|                         |                  |                      |
| User entered 'Anderson' | System           | 04 Nov 2020 17:43:27 |

US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:30

Site Address: [Street](#)

| Audit                               | User             | Time (GMT)           |
|-------------------------------------|------------------|----------------------|
| Reviewed for Safety.                | (b) (4), (b) (6) | 04 Nov 2020 17:43:53 |
|                                     |                  |                      |
| User entered '2015 Uppergate Drive' | System           | 04 Nov 2020 17:43:27 |



US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:30

Site Address: [City](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| Reviewed for Safety.   | (b) (4), (b) (6) | 04 Nov 2020 17:43:53 |
|                        |                  |                      |
| User entered 'Atlanta' | System           | 04 Nov 2020 17:43:27 |

US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:30

[Site Address: State](#)

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 04 Nov 2020 17:43:53 |
|                      |                  |                      |
| User entered 'GA'    | System           | 04 Nov 2020 17:43:27 |

US3532063

**Folder:** SAE USA-US077-2020-MRNA-1273-P301000007

**Form:** Safety Report Form

**Generated On:** 26 Nov 2020 09:35:30

[Site Address: Postal Code](#)

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 04 Nov 2020 17:43:53 |
|                      |                  |                      |
| User entered '30323' | System           | 04 Nov 2020 17:43:27 |

US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:30

[Investigator Country](#)

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 17 Nov 2020 14:43:41 |
|                      |                  |                      |
| User entered 'US'    | System           | 04 Nov 2020 17:44:05 |

US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:30

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '3' | System | 18 Nov 2020 13:46:43 |
| User entered '2' | System | 17 Nov 2020 14:43:50 |
| User entered '1' | System | 04 Nov 2020 17:44:05 |

US3532063

**Folder:** SAE USA-US077-2020-MRNA-1273-P301000007

**Form:** Safety Report Form (1)

**Generated On:** 26 Nov 2020 09:35:30

[Date of submission \(Pre-filled from custom function\)](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '04/Nov/2020 12:44' | System | 04 Nov 2020 17:44:05 |

US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 09:35:30

**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) | 17 Nov 2020 14:43:41 |
|                      |                  |                      |
| User entered '1'     | (b) (4), (b) (6) | 04 Nov 2020 17:44:05 |
|                      |                  |                      |
|                      |                  |                      |

US3532063

**Folder:** SAE USA-US077-2020-MRNA-1273-P301000007

**Form:** Safety Report Form

**Generated On:** 26 Nov 2020 09:35:30

[SAEID](#)

| Audit                                                 | User             | Time (GMT)           |
|-------------------------------------------------------|------------------|----------------------|
| Reviewed for Safety.                                  | (b) (4), (b) (6) | 04 Nov 2020 17:43:53 |
|                                                       |                  |                      |
| User entered<br>'USA-US077-2020-MRNA-1273-P301000007' | System           | 04 Nov 2020 17:43:27 |



US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:30

Serious

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| Reviewed for Safety.   | (b) (4), (b) (6) | 04 Nov 2020 17:43:53 |
|                        |                  |                      |
| User entered 'Yes (Y)' | System           | 04 Nov 2020 17:43:27 |

US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:30

[Death](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| Reviewed for Safety.  | (b) (4), (b) (6) | 04 Nov 2020 17:43:53 |
|                       |                  |                      |
| User entered 'No (N)' | System           | 04 Nov 2020 17:43:27 |

US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:30

[Life threatening](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| Reviewed for Safety.  | (b) (4), (b) (6) | 04 Nov 2020 17:43:53 |
|                       |                  |                      |
| User entered 'No (N)' | System           | 04 Nov 2020 17:43:27 |

US3532063

**Folder:** SAE USA-US077-2020-MRNA-1273-P301000007

**Form:** Safety Report Form

**Generated On:** 26 Nov 2020 09:35:30

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| Reviewed for Safety.   | (b) (4), (b) (6) | 04 Nov 2020 17:43:53 |
|                        |                  |                      |
| User entered 'Yes (Y)' | System           | 04 Nov 2020 17:43:27 |

US3532063

**Folder:** SAE USA-US077-2020-MRNA-1273-P301000007

**Form:** Safety Report Form

**Generated On:** 26 Nov 2020 09:35:30

[Persistent or significant disability or incapacity](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| Reviewed for Safety.  | (b) (4), (b) (6) | 04 Nov 2020 17:43:53 |
|                       |                  |                      |
| User entered 'No (N)' | System           | 04 Nov 2020 17:43:27 |

US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:30

[Congenital anomaly or birth defect](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| Reviewed for Safety.  | (b) (4), (b) (6) | 04 Nov 2020 17:43:53 |
|                       |                  |                      |
| User entered 'No (N)' | System           | 04 Nov 2020 17:43:27 |

US3532063

**Folder:** SAE USA-US077-2020-MRNA-1273-P301000007

**Form:** Safety Report Form

**Generated On:** 26 Nov 2020 09:35:30

[Other medically important event](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| Reviewed for Safety.  | (b) (4), (b) (6) | 04 Nov 2020 17:43:53 |
|                       |                  |                      |
| User entered 'No (N)' | System           | 04 Nov 2020 17:43:27 |

US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:30

[Investigator's First Name](#)

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 04 Nov 2020 17:43:53 |
|                      |                  |                      |
| User entered 'Evan'  | System           | 04 Nov 2020 17:43:27 |



US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:30

[Investigator's Last Name](#)

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| Reviewed for Safety.    | (b) (4), (b) (6) | 04 Nov 2020 17:43:53 |
|                         |                  |                      |
| User entered 'Anderson' | System           | 04 Nov 2020 17:43:27 |

US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:30

Site Address: [Street](#)

| Audit                               | User             | Time (GMT)           |
|-------------------------------------|------------------|----------------------|
| Reviewed for Safety.                | (b) (4), (b) (6) | 04 Nov 2020 17:43:53 |
|                                     |                  |                      |
| User entered '2015 Uppergate Drive' | System           | 04 Nov 2020 17:43:27 |

US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:30

Site Address: [City](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| Reviewed for Safety.   | (b) (4), (b) (6) | 04 Nov 2020 17:43:53 |
|                        |                  |                      |
| User entered 'Atlanta' | System           | 04 Nov 2020 17:43:27 |

US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:30

Site Address: [State](#)

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 04 Nov 2020 17:43:53 |
|                      |                  |                      |
| User entered 'GA'    | System           | 04 Nov 2020 17:43:27 |

US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:30

Site Address: [Postal Code](#)

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 04 Nov 2020 17:43:53 |
|                      |                  |                      |
| User entered '30323' | System           | 04 Nov 2020 17:43:27 |

US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:30

[Investigator Country](#)

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 17 Nov 2020 14:43:41 |
|                      |                  |                      |
| User entered 'US'    | System           | 04 Nov 2020 17:44:05 |

US3532063

**Folder:** SAE USA-US077-2020-MRNA-1273-P301000007

**Form:** Safety Report Form

**Generated On:** 26 Nov 2020 09:35:30

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '3' | System | 18 Nov 2020 13:46:43 |
| User entered '2' | System | 17 Nov 2020 14:43:50 |
| User entered '1' | System | 04 Nov 2020 17:44:05 |

US3532063

**Folder:** SAE USA-US077-2020-MRNA-1273-P301000007

**Form:** Safety Report Form (2)

**Generated On:** 26 Nov 2020 09:35:30

[Date of submission \(Pre-filled from custom function\)](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '17/Nov/2020 09:43' | System | 17 Nov 2020 14:43:50 |



US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 09:35:30

**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) | 18 Nov 2020 13:46:18 |
|                      |                  |                      |
| User entered '1'     | (b) (4), (b) (6) | 17 Nov 2020 14:43:50 |
|                      |                  |                      |
|                      |                  |                      |

US3532063

**Folder:** SAE USA-US077-2020-MRNA-1273-P301000007

**Form:** Safety Report Form

**Generated On:** 26 Nov 2020 09:35:30

[SAEID](#)

| Audit                                                 | User             | Time (GMT)           |
|-------------------------------------------------------|------------------|----------------------|
| Reviewed for Safety.                                  | (b) (4), (b) (6) | 04 Nov 2020 17:43:53 |
|                                                       |                  |                      |
| User entered<br>'USA-US077-2020-MRNA-1273-P301000007' | System           | 04 Nov 2020 17:43:27 |

US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:30

Serious

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| Reviewed for Safety.   | (b) (4), (b) (6) | 04 Nov 2020 17:43:53 |
|                        |                  |                      |
| User entered 'Yes (Y)' | System           | 04 Nov 2020 17:43:27 |

US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:30

[Death](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| Reviewed for Safety.  | (b) (4), (b) (6) | 04 Nov 2020 17:43:53 |
|                       |                  |                      |
| User entered 'No (N)' | System           | 04 Nov 2020 17:43:27 |

US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:30

[Life threatening](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| Reviewed for Safety.  | (b) (4), (b) (6) | 04 Nov 2020 17:43:53 |
|                       |                  |                      |
| User entered 'No (N)' | System           | 04 Nov 2020 17:43:27 |

US3532063

**Folder:** SAE USA-US077-2020-MRNA-1273-P301000007

**Form:** Safety Report Form

**Generated On:** 26 Nov 2020 09:35:30

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| Reviewed for Safety.   | (b) (4), (b) (6) | 04 Nov 2020 17:43:53 |
|                        |                  |                      |
| User entered 'Yes (Y)' | System           | 04 Nov 2020 17:43:27 |

US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:30

[Persistent or significant disability or incapacity](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| Reviewed for Safety.  | (b) (4), (b) (6) | 04 Nov 2020 17:43:53 |
|                       |                  |                      |
| User entered 'No (N)' | System           | 04 Nov 2020 17:43:27 |

US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:30

[Congenital anomaly or birth defect](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| Reviewed for Safety.  | (b) (4), (b) (6) | 04 Nov 2020 17:43:53 |
|                       |                  |                      |
| User entered 'No (N)' | System           | 04 Nov 2020 17:43:27 |



US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:30

[Other medically important event](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| Reviewed for Safety.  | (b) (4), (b) (6) | 04 Nov 2020 17:43:53 |
|                       |                  |                      |
| User entered 'No (N)' | System           | 04 Nov 2020 17:43:27 |

US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:30

[Investigator's First Name](#)

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 04 Nov 2020 17:43:53 |
|                      |                  |                      |
| User entered 'Evan'  | System           | 04 Nov 2020 17:43:27 |

US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:30

[Investigator's Last Name](#)

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| Reviewed for Safety.    | (b) (4), (b) (6) | 04 Nov 2020 17:43:53 |
|                         |                  |                      |
| User entered 'Anderson' | System           | 04 Nov 2020 17:43:27 |

US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:30

Site Address: [Street](#)

| Audit                               | User             | Time (GMT)           |
|-------------------------------------|------------------|----------------------|
| Reviewed for Safety.                | (b) (4), (b) (6) | 04 Nov 2020 17:43:53 |
|                                     |                  |                      |
| User entered '2015 Uppergate Drive' | System           | 04 Nov 2020 17:43:27 |

US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:30

Site Address: [City](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| Reviewed for Safety.   | (b) (4), (b) (6) | 04 Nov 2020 17:43:53 |
|                        |                  |                      |
| User entered 'Atlanta' | System           | 04 Nov 2020 17:43:27 |

US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:30

Site Address: [State](#)

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 04 Nov 2020 17:43:53 |
|                      |                  |                      |
| User entered 'GA'    | System           | 04 Nov 2020 17:43:27 |

US3532063

**Folder:** SAE USA-US077-2020-MRNA-1273-P301000007

**Form:** Safety Report Form

**Generated On:** 26 Nov 2020 09:35:30

[Site Address: Postal Code](#)

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 04 Nov 2020 17:43:53 |
|                      |                  |                      |
| User entered '30323' | System           | 04 Nov 2020 17:43:27 |

US3532063

**Folder:** SAE USA-US077-2020-MRNA-1273-P301000007

**Form:** Safety Report Form

**Generated On:** 26 Nov 2020 09:35:30

[Investigator Country](#)

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 17 Nov 2020 14:43:41 |
|                      |                  |                      |
| User entered 'US'    | System           | 04 Nov 2020 17:44:05 |



US3532063

**Folder:** SAE USA-US077-2020-MRNA-1273-P301000007

**Form:** Safety Report Form

**Generated On:** 26 Nov 2020 09:35:30

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '3' | System | 18 Nov 2020 13:46:43 |
| User entered '2' | System | 17 Nov 2020 14:43:50 |
| User entered '1' | System | 04 Nov 2020 17:44:05 |

US3532063

**Folder:** SAE USA-US077-2020-MRNA-1273-P301000007

**Form:** Safety Report Form (3)

**Generated On:** 26 Nov 2020 09:35:30

[Date of submission \(Pre-filled from custom function\)](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '18/Nov/2020 08:46' | System | 18 Nov 2020 13:46:43 |

US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 09:35:30

**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) | 18 Nov 2020 13:46:43 |
|                  |                  |                      |
|                  |                  |                      |