

US3762161 (Prod: Wake Forest University Health Sciences)

Generated By: KC Joubran

Generated On: 26 Nov 2020 11:14:36

All time stamps listed in this document are displayed in GMT

US3762161

Form: Participant Creation

Generated On: 26 Nov 2020 11:14:36

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[Participant ID](#)

US3762161

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

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US3762161

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:14:36

|                                                                 |                                         |
|-----------------------------------------------------------------|-----------------------------------------|
| Was this visit performed?                                       | Yes <input checked="" type="radio"/>    |
|                                                                 | No <input type="radio"/>                |
| Visit date (dd MMM yyyy)                                        | 02 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                                                      | SCRN                                    |

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Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:14:36

|                                           |                                                                                                                                                                            |
|-------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Date of Birth (MMM yyyy)                  | (b) (6) 1946                                                                                                                                                               |
| Age                                       | 74                                                                                                                                                                         |
| Age Units                                 | YEARS                                                                                                                                                                      |
| Age (Derived)                             | 74                                                                                                                                                                         |
| Sex                                       | Female <input type="radio"/><br>Male <input checked="" type="radio"/>                                                                                                      |
| Ethnicity                                 | Hispanic or Latino <input type="radio"/><br>Not Hispanic or Latino <input checked="" type="radio"/><br>Not Reported <input type="radio"/><br>Unknown <input type="radio"/> |
| Race (Check All That Apply)               |                                                                                                                                                                            |
| White                                     | 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 11:14:36

|                                                 |                                              |
|-------------------------------------------------|----------------------------------------------|
| Date of Informed Consent ( <i>dd MMM yyyy</i> ) | 02 SEP 2020                                  |
| Month and Year of Informed Consent (derived)    | SEP 2020                                     |
| Year of Informed Consent (derived)              | 2020                                         |
| Protocol Version                                | Amendment 1 <input type="radio"/>            |
|                                                 | Amendment 2 <input type="radio"/>            |
|                                                 | Amendment 3 <input checked="" type="radio"/> |
|                                                 | Amendment 4 <input type="radio"/>            |
|                                                 | Amendment 5 <input type="radio"/>            |
| Was participant enrolled in the study?          | Yes <input checked="" type="radio"/>         |
|                                                 | No <input type="radio"/>                     |
| If No, indicate reason for screen fail          | Withdrew Consent <input type="radio"/>       |
|                                                 | Inclusion/Exclusion <input type="radio"/>    |
|                                                 | Cohort Full <input type="radio"/>            |
|                                                 | Other <input type="radio"/>                  |
| If reason for screen fail is Other, specify     |                                              |
| Was this participant screened previously?       | Yes <input type="radio"/>                    |
|                                                 | No <input checked="" type="radio"/>          |
| If Yes, previous participant number             |                                              |
| Enrollment Trigger                              | 1                                            |

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 11:14:36

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 11:14:36

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Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:14:36

|                                                   |                                                                  |
|---------------------------------------------------|------------------------------------------------------------------|
| Condition                                         | CATARACTS - BILATERAL                                            |
| Start date (dd MMM yyyy)                          | UN UNK 2016                                                      |
| 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 2016                                                         |
| Start Year (derived)                              | 2016                                                             |
| Stop Month and Year (derived)                     | JAN 2017                                                         |
| Stop Year (derived)                               | 2017                                                             |



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Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:14:36

|                                                   |                                                                  |
|---------------------------------------------------|------------------------------------------------------------------|
| Condition                                         | DIABETES                                                         |
| Start date (dd MMM yyyy)                          | UN UNK 1998                                                      |
| 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 1998                                                         |
| Start Year (derived)                              | 1998                                                             |
| Stop Month and Year (derived)                     |                                                                  |
| Stop Year (derived)                               |                                                                  |

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Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:14:36

|                                                   |                                                                  |
|---------------------------------------------------|------------------------------------------------------------------|
| Condition                                         | HIGH CHOLESTEROL                                                 |
| 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 (4)

Generated On: 26 Nov 2020 11:14:36

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

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Form: Medical History (5)

Generated On: 26 Nov 2020 11:14:36

|                                                         |                                                                  |
|---------------------------------------------------------|------------------------------------------------------------------|
| Condition                                               | TREMORS                                                          |
| Start date (dd MMM yyyy)                                | UN UNK 2011                                                      |
| 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 2011                                                         |
| Start Year (derived)                                    | 2011                                                             |
| Stop Month and Year (derived)                           | _____                                                            |
| Stop Year (derived)                                     | _____                                                            |

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Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:14:36

|                                                   |                                                                  |
|---------------------------------------------------|------------------------------------------------------------------|
| Condition                                         | DIABETIC NEUROPATHY                                              |
| Start date (dd MMM yyyy)                          | UN UNK 1998                                                      |
| 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 1998                                                         |
| Start Year (derived)                              | 1998                                                             |
| Stop Month and Year (derived)                     |                                                                  |
| Stop Year (derived)                               |                                                                  |

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Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:14:36

|                                                   |                                                                  |
|---------------------------------------------------|------------------------------------------------------------------|
| Condition                                         | STROKE - CEREBELLUM                                              |
| Start date (dd MMM yyyy)                          | UN UNK 2006                                                      |
| 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 2006                                                      |
| Stop date completely unknown                      | False                                                            |
| Start Month and Year (derived)                    | JAN 2006                                                         |
| Start Year (derived)                              | 2006                                                             |
| Stop Month and Year (derived)                     | JAN 2006                                                         |
| Stop Year (derived)                               | 2006                                                             |

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Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:14:36

|                                                   |                                                                  |
|---------------------------------------------------|------------------------------------------------------------------|
| Condition                                         | HEART ATTACK                                                     |
| Start date (dd MMM yyyy)                          | UN UNK 2007                                                      |
| 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 2007                                                      |
| Stop date completely unknown                      | False                                                            |
| Start Month and Year (derived)                    | JAN 2007                                                         |
| Start Year (derived)                              | 2007                                                             |
| Stop Month and Year (derived)                     | JAN 2007                                                         |
| Stop Year (derived)                               | 2007                                                             |

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Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:14:36

|                                                   |                                                                  |
|---------------------------------------------------|------------------------------------------------------------------|
| Condition                                         | KIDNEY STONES                                                    |
| Start date (dd MMM yyyy)                          | UN UNK 1995                                                      |
| 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 1995                                                         |
| Start Year (derived)                              | 1995                                                             |
| Stop Month and Year (derived)                     | JAN 2017                                                         |
| Stop Year (derived)                               | 2017                                                             |



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Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:14:36

|                                                   |                                                                  |
|---------------------------------------------------|------------------------------------------------------------------|
| Condition                                         | VASECTOMY                                                        |
| Start date (dd MMM yyyy)                          | UN UNK 1981                                                      |
| 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 1981                                                      |
| Stop date completely unknown                      | False                                                            |
| Start Month and Year (derived)                    | JAN 1981                                                         |
| Start Year (derived)                              | 1981                                                             |
| Stop Month and Year (derived)                     | JAN 1981                                                         |
| Stop Year (derived)                               | 1981                                                             |

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Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:14:36

|                                           |                                      |
|-------------------------------------------|--------------------------------------|
| Were vital signs assessed?                | Yes <input checked="" type="radio"/> |
|                                           | No <input type="radio"/>             |
| Date of assessment ( <i>dd MMM yyyy</i> ) | 2 SEP 2020                           |
| Time of assessment ( <i>00:00-23:59</i> ) | 14:22 (24 HR)                        |
| Vital Signs Date and Time (derived)       | 2 SEP 2020 14:22                     |
| Height ( <i>xxx.x</i> )                   | 68 in                                |
| Weight ( <i>xxx.x</i> )                   | 205 lb                               |
| BMI ( <i>xxx.x</i> )                      | 31.23532 kg/m <sup>2</sup>           |
| BMI units                                 | KG/M2                                |
| Temperature ( <i>xxx.x</i> )              | ND - Not Done                        |
| Route of measurement                      | Oral <input type="radio"/>           |
|                                           | Axillary <input type="radio"/>       |
|                                           | Other <input type="radio"/>          |
| If Other, specify                         |                                      |
| Pulse ( <i>xxx</i> )                      | ND - Not Done                        |
| Pulse units                               | BPM                                  |
| Respiratory Rate ( <i>xxx</i> )           | ND - Not Done                        |
| Respiratory Rate units                    | BREATHS/MIN                          |
| Systolic Blood Pressure ( <i>xxx</i> )    | ND - Not Done                        |
| Systolic Blood Pressure units             | MMHG                                 |
| Diastolic Blood Pressure ( <i>xxx</i> )   | ND - Not Done                        |
| Diastolic Blood Pressure units            | MMHG                                 |
| Height (derived)                          |                                      |
| Weight (derived)                          |                                      |

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Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 11:14:36

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

2 SEP 2020

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

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Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:14:36

#### 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>                                                                                                                    | True  |
| <b>Resides in Nursing Home or Assisted Living Facility</b>                                                                                   | False |
| <b>Resides in Multi-family dwelling</b> (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs) | False |

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Folder: Screening

Form: Risk of Exposure

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

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:14:36

|                                                                 |                                         |
|-----------------------------------------------------------------|-----------------------------------------|
| Was this visit performed?                                       | Yes <input checked="" type="radio"/>    |
|                                                                 | No <input type="radio"/>                |
| Visit date (dd MMM yyyy)                                        | 02 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                                                      | VISIT1                                  |

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:14:36

What was the date of randomization? (dd MMM yyyy) 02 SEP 2020

What was the participant's randomization number? 189561

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:14:36

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



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:14:36

|                                     |                                                                                                        |
|-------------------------------------|--------------------------------------------------------------------------------------------------------|
| 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)    | 02 SEP 2020                                                                                            |
| Time of assessment (00:00-23:59)    | 14:22 (24 HR)                                                                                          |
| Vital Signs Date and Time (derived) | 02 SEP 2020 14:22                                                                                      |
| Temperature (xxx.x)                 | 97.0 F                                                                                                 |
| Route of measurement                | Oral <input checked="" type="radio"/><br>Axillary <input type="radio"/><br>Other <input type="radio"/> |
| If Other, specify                   |                                                                                                        |
| Pulse (xxx)                         | 77 beats/min                                                                                           |
| Pulse units                         | BPM                                                                                                    |
| Respiratory Rate (xxx)              | 16 breaths/min                                                                                         |
| Respiratory Rate units              | BREATHS/MIN                                                                                            |
| Systolic Blood Pressure (xxx)       | 135 mmHg                                                                                               |
| Systolic Blood Pressure units       | MMHG                                                                                                   |
| Diastolic Blood Pressure (xxx)      | 79 mmHg                                                                                                |
| Diastolic Blood Pressure units      | MMHG                                                                                                   |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:14:36

|                                     |                                                                                                        |
|-------------------------------------|--------------------------------------------------------------------------------------------------------|
| 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)    | 02 SEP 2020                                                                                            |
| Time of assessment (00:00-23:59)    | 15:50 (24 HR)                                                                                          |
| Vital Signs Date and Time (derived) | 02 SEP 2020 15:50                                                                                      |
| 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)                         | 71 beats/min                                                                                           |
| Pulse units                         | BPM                                                                                                    |
| Respiratory Rate (xxx)              | 17 breaths/min                                                                                         |
| Respiratory Rate units              | BREATHS/MIN                                                                                            |
| Systolic Blood Pressure (xxx)       | 138 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 11:14:36

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

02 SEP 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 11:14:36

|                                                                                                              |                                                      |
|--------------------------------------------------------------------------------------------------------------|------------------------------------------------------|
| Was study treatment given?                                                                                   | Yes <input checked="" type="radio"/>                 |
|                                                                                                              | No <input type="radio"/>                             |
| If No, reason not given                                                                                      | Participant declined due to <input type="radio"/>    |
|                                                                                                              | Adverse Event <input type="radio"/>                  |
|                                                                                                              | Physician withheld dose due to <input type="radio"/> |
|                                                                                                              | Adverse Event <input type="radio"/>                  |
|                                                                                                              | Death <input type="radio"/>                          |
|                                                                                                              | Lost To Follow-Up <input type="radio"/>              |
|                                                                                                              | Physician Decision <input type="radio"/>             |
|                                                                                                              | Pregnancy <input type="radio"/>                      |
|                                                                                                              | Protocol Deviation <input type="radio"/>             |
|                                                                                                              | Study Terminated by Sponsor <input type="radio"/>    |
|                                                                                                              | Withdrawal of Consent by <input type="radio"/>       |
|                                                                                                              | Participant <input type="radio"/>                    |
|                                                                                                              | Confirmed COVID-19 <input type="radio"/>             |
|                                                                                                              | Other <input type="radio"/>                          |
| If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify |                                                      |
| What was the study treatment?                                                                                | MRNA-1273 OR PLACEBO                                 |
| What was the treatment date? (dd MMM yyyy)                                                                   | 02 SEP 2020                                          |
| What was the treatment time? (00:00-23:59)                                                                   | 15:12 (24 HR)                                        |
| Treatment Date and Time (derived)                                                                            | 02 SEP 2020 15:12                                    |
| Which arm was used to give treatment?                                                                        | Left Arm <input checked="" type="radio"/>            |
|                                                                                                              | Right Arm <input type="radio"/>                      |
| 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 11:14:36

Was the sample collected?

Yes ☒

No ☐

Collection date (*dd MMM yyyy*)

02 SEP 2020

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

14:59 (24 HR)

Collection date and time (derived)

02 SEP 2020 14:59

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 11:14:36

|                                        |                           |                                          |                                    |
|----------------------------------------|---------------------------|------------------------------------------|------------------------------------|
| Collection date ( <i>dd MMM yyyy</i> ) |                           |                                          | 02 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                       | 14:55                                    | 02 SEP 2020 14:55                  |
| Nasopharyngeal Swab 2                  | No                        |                                          |                                    |

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Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 11:14:36

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 26 Nov 2020 11:14:36

**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

97.4 °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

02 SEP 2020 15:55

PC Open Date & Time

02 SEP 2020 15:32

PC Close Date & Time

02 SEP 2020 18:02



US3762161

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 26 Nov 2020 11:14:36

**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**

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

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time 02 SEP 2020 18:57

PC Close Date & Time 03 SEP 2020 11:59

US3762161

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 11:14:36

**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

97.7 °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

03 SEP 2020 14:32

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3762161

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 26 Nov 2020 11:14:36

**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

97.2 °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

04 SEP 2020 21:08

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3762161

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 11:14:36

**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

96.1 °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

05 SEP 2020 21:58

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3762161

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 26 Nov 2020 11:14:36

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**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

96.7 °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

06 SEP 2020 22:53

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3762161

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 26 Nov 2020 11:14:36

**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

96.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

07 SEP 2020 21:40

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3762161

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 26 Nov 2020 11:14:36

**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

95.1 °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

08 SEP 2020 22:47

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3762161

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 11:14:36

**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

02 SEP 2020 15:56

PC Open Date & Time

02 SEP 2020 15:32

PC Close Date & Time

02 SEP 2020 18:02



US3762161

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 26 Nov 2020 11:14:36

**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 ☐

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

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

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

Yes ☐

No ☐

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

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

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

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

PC Open Date & Time

02 SEP 2020 18:57

PC Close Date & Time

03 SEP 2020 11:59

US3762161

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 26 Nov 2020 11:14:36

**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

03 SEP 2020 14:33

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3762161

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 26 Nov 2020 11:14:36

**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

04 SEP 2020 21:08

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3762161

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 26 Nov 2020 11:14:36

**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

05 SEP 2020 21:58

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3762161

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 26 Nov 2020 11:14:36

**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

06 SEP 2020 22:54

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3762161

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 26 Nov 2020 11:14:36

**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

07 SEP 2020 21:40

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3762161

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 26 Nov 2020 11:14:36

**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

08 SEP 2020 22:47

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3762161

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 11:14:36

**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 ☐



US3762161

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 11:14:36

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

No ☒

Yes ☐

|                      |                   |
|----------------------|-------------------|
| PC Time stamp        | 02 SEP 2020 15:58 |
| PC Open Date & Time  | 02 SEP 2020 15:32 |
| PC Close Date & Time | 02 SEP 2020 18:02 |

US3762161

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 11:14:36

**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 ☐

US3762161

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 11:14:36

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

02 SEP 2020 18:57

PC Close Date & Time

03 SEP 2020 11:59

US3762161

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 11:14:36

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 ☒

US3762161

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 11:14:36

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 03 SEP 2020 14:33 |
| PC Open Date & Time          | 03 SEP 2020 12:00 |
| PC Close Date & Time         | 04 SEP 2020 11:59 |

US3762161

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 11:14:36

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 ☒

US3762161

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 11:14:36

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 04 SEP 2020 21:09 |
| PC Open Date & Time          | 04 SEP 2020 12:00 |
| PC Close Date & Time         | 05 SEP 2020 11:59 |

US3762161

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 11:14:36

**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 ☒



US3762161

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 11:14:36

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 05 SEP 2020 21:59 |
| PC Open Date & Time          | 05 SEP 2020 12:00 |
| PC Close Date & Time         | 06 SEP 2020 11:59 |

US3762161

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 11:14:36

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 ☒

US3762161

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 11:14:36

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 06 SEP 2020 22:54 |
| PC Open Date & Time          | 06 SEP 2020 12:00 |
| PC Close Date & Time         | 07 SEP 2020 11:59 |

US3762161

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 11:14:36

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 ☒

US3762161

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 11:14:36

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 07 SEP 2020 21:41 |
| PC Open Date & Time          | 07 SEP 2020 12:00 |
| PC Close Date & Time         | 08 SEP 2020 11:59 |

US3762161

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 11:14:36

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 ☒

US3762161

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 11:14:36

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 08 SEP 2020 22:47 |
| PC Open Date & Time          | 08 SEP 2020 12:00 |
| PC Close Date & Time         | 09 SEP 2020 11:59 |

US3762161

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:14:36

Was Contact Attempted?

Yes ☒

No ☐

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

09 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3762161

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:14:36

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3762161

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:14:36

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

16 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3762161

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:14:36

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3762161

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:14:36

Was Contact Attempted?

Yes ☒

No ☐

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

23 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3762161

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:14:36

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3762161

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:14:36

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

US3762161

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:14:36

|                                     |                                           |
|-------------------------------------|-------------------------------------------|
| 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)    | 30 SEP 2020                               |
| Time of assessment (00:00-23:59)    | 15:13 (24 HR)                             |
| Vital Signs Date and Time (derived) | 30 SEP 2020 15:13                         |
| Temperature (xxx.x)                 | 98.9 F                                    |
| Route of measurement                | Oral <input checked="" type="radio"/>     |
|                                     | Axillary <input type="radio"/>            |
|                                     | Other <input type="radio"/>               |
| If Other, specify                   |                                           |
| Pulse (xxx)                         | 81 beats/min                              |
| Pulse units                         | BPM                                       |
| Respiratory Rate (xxx)              | 15 breaths/min                            |
| Respiratory Rate units              | BREATHS/MIN                               |
| Systolic Blood Pressure (xxx)       | 121 mmHg                                  |
| Systolic Blood Pressure units       | MMHG                                      |
| Diastolic Blood Pressure (xxx)      | 70 mmHg                                   |
| Diastolic Blood Pressure units      | MMHG                                      |

US3762161

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:14:36

|                                     |                                            |
|-------------------------------------|--------------------------------------------|
| 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)    | 30 SEP 2020                                |
| Time of assessment (00:00-23:59)    | 16:20 (24 HR)                              |
| Vital Signs Date and Time (derived) | 30 SEP 2020 16:20                          |
| Temperature (xxx.x)                 | 98.2 F                                     |
| Route of measurement                | Oral <input checked="" type="radio"/>      |
|                                     | Axillary <input type="radio"/>             |
|                                     | Other <input type="radio"/>                |
| If Other, specify                   |                                            |
| Pulse (xxx)                         | 76 beats/min                               |
| Pulse units                         | BPM                                        |
| Respiratory Rate (xxx)              | ND - Not Done                              |
| Respiratory Rate units              | BREATHS/MIN                                |
| Systolic Blood Pressure (xxx)       | 113 mmHg                                   |
| Systolic Blood Pressure units       | MMHG                                       |
| Diastolic Blood Pressure (xxx)      | 64 mmHg                                    |
| Diastolic Blood Pressure units      | MMHG                                       |



US3762161

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:14:36

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

30 SEP 2020

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

US3762161

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:14:36

|                                                                                                              |                                                                    |
|--------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------|
| Was study treatment given?                                                                                   | Yes <input checked="" type="radio"/>                               |
|                                                                                                              | No <input type="radio"/>                                           |
| If No, reason not given                                                                                      | Participant declined due to Adverse Event <input type="radio"/>    |
|                                                                                                              | Physician withheld dose due to Adverse Event <input type="radio"/> |
|                                                                                                              | Death <input type="radio"/>                                        |
|                                                                                                              | Lost To Follow-Up <input type="radio"/>                            |
|                                                                                                              | Physician Decision <input type="radio"/>                           |
|                                                                                                              | Pregnancy <input type="radio"/>                                    |
|                                                                                                              | Protocol Deviation <input type="radio"/>                           |
|                                                                                                              | Study Terminated by Sponsor <input type="radio"/>                  |
|                                                                                                              | Withdrawal of Consent by Participant <input type="radio"/>         |
|                                                                                                              | Confirmed COVID-19 <input type="radio"/>                           |
|                                                                                                              | Other <input type="radio"/>                                        |
| If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify |                                                                    |
| What was the study treatment?                                                                                | MRNA-1273 OR PLACEBO                                               |
| What was the treatment date? (dd MMM yyyy)                                                                   | 30 SEP 2020                                                        |
| What was the treatment time? (00:00-23:59)                                                                   | 15:30 (24 HR)                                                      |
| Treatment Date and Time (derived)                                                                            | 30 SEP 2020 15:30                                                  |
| Which arm was used to give treatment?                                                                        | Left Arm <input checked="" type="radio"/>                          |
|                                                                                                              | Right Arm <input type="radio"/>                                    |
| What was the frequency of the study treatment dosing?                                                        | ONCE                                                               |
| What was the route of administration for the study treatment?                                                | INTRAMUSCULAR                                                      |

US3762161

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:14:36

Was the sample collected?

Yes ☒

No ☐

Collection date (*dd MMM yyyy*)

30 SEP 2020

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

15:16 (24 HR)

Collection date and time (derived)

30 SEP 2020 15:16

US3762161

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 11:14:36

| Collection date (dd MMM yyyy) |                           |                                 | 30 SEP 2020                        |
|-------------------------------|---------------------------|---------------------------------|------------------------------------|
| Lab Test                      | Was the sample collected? | Collection time (00:00 - 23:59) | Collection date and time (derived) |
| Nasopharyngeal Swab 1         | Yes                       | 15:26                           | 30 SEP 2020 15:26                  |
| Nasopharyngeal Swab 2         | No                        |                                 |                                    |

US3762161

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:14:36

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3762161

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 26 Nov 2020 11:14:36

**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

98.2 °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

30 SEP 2020 16:27

PC Open Date & Time

30 SEP 2020 15:50

PC Close Date & Time

30 SEP 2020 18:20

US3762161

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 26 Nov 2020 11:14:36

**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 96.2 °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        | 30 SEP 2020 23:04 |
| PC Open Date & Time  | 30 SEP 2020 19:15 |
| PC Close Date & Time | 01 OCT 2020 11:59 |

US3762161

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 11:14:36

**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

02 OCT 2020 02:29

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59



US3762161

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 26 Nov 2020 11:14:36

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**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

97.5 °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 02 OCT 2020 22:54

PC Open Date & Time 02 OCT 2020 12:00

PC Close Date & Time 03 OCT 2020 11:59

US3762161

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 11:14:36

**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

97.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

03 OCT 2020 23:07

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3762161

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 26 Nov 2020 11:14:36

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**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

96.8 °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

04 OCT 2020 21:16

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3762161

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 26 Nov 2020 11:14:36

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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

96.5 °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

06 OCT 2020 09:43

PC Open Date & Time

05 OCT 2020 12:00

PC Close Date & Time

06 OCT 2020 11:59

US3762161

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 26 Nov 2020 11:14:36

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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

96.5 °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

06 OCT 2020 21:30

PC Open Date & Time

06 OCT 2020 12:00

PC Close Date & Time

07 OCT 2020 11:59

US3762161

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 11:14:36

**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

30 SEP 2020 16:27

PC Open Date & Time

30 SEP 2020 15:50

PC Close Date & Time

30 SEP 2020 18:20

US3762161

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 26 Nov 2020 11:14:36

**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

30 SEP 2020 23:05

PC Open Date & Time

30 SEP 2020 19:15

PC Close Date & Time

01 OCT 2020 11:59

US3762161

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 26 Nov 2020 11:14:36

**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

02 OCT 2020 02:30

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59



US3762161

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 26 Nov 2020 11:14:36

**TIMEPOINT**

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☒

No ☐

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

7

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

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

Yes ☒

No ☐

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

3

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

02 OCT 2020 22:59

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3762161

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 26 Nov 2020 11:14:36

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

3

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

03 OCT 2020 23:08

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3762161

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 26 Nov 2020 11:14:36

**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

04 OCT 2020 21:17

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3762161

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 26 Nov 2020 11:14:36

**TIMEPOINT**

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

06 OCT 2020 09:44

PC Open Date & Time

05 OCT 2020 12:00

PC Close Date & Time

06 OCT 2020 11:59

US3762161

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 26 Nov 2020 11:14:36

**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

06 OCT 2020 21:30

PC Open Date & Time

06 OCT 2020 12:00

PC Close Date & Time

07 OCT 2020 11:59

US3762161

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 11:14:36

**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 ☐

US3762161

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 11:14:36

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

No ☒

Yes ☐

|                      |                   |
|----------------------|-------------------|
| PC Time stamp        | 30 SEP 2020 16:28 |
| PC Open Date & Time  | 30 SEP 2020 15:50 |
| PC Close Date & Time | 30 SEP 2020 18:20 |

US3762161

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 11:14:36

**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 ☐



US3762161

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 11:14:36

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

No ☒

Yes ☐

|                      |                   |
|----------------------|-------------------|
| PC Time stamp        | 30 SEP 2020 23:05 |
| PC Open Date & Time  | 30 SEP 2020 19:15 |
| PC Close Date & Time | 01 OCT 2020 11:59 |

US3762161

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 11:14:36

**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 ☒

US3762161

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 11:14:36

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 02 OCT 2020 02:31 |
| PC Open Date & Time          | 01 OCT 2020 12:00 |
| PC Close Date & Time         | 02 OCT 2020 11:59 |

US3762161

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 11:14:36

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 ☒

US3762161

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 11:14:36

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 02 OCT 2020 22:59 |
| PC Open Date & Time          | 02 OCT 2020 12:00 |
| PC Close Date & Time         | 03 OCT 2020 11:59 |

US3762161

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 11:14:36

**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 ☒

US3762161

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 11:14:36

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 03 OCT 2020 23:08 |
| PC Open Date & Time          | 03 OCT 2020 12:00 |
| PC Close Date & Time         | 04 OCT 2020 11:59 |

US3762161

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 11:14:36

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 ☒



US3762161

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 11:14:36

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 04 OCT 2020 21:17 |
| PC Open Date & Time          | 04 OCT 2020 12:00 |
| PC Close Date & Time         | 05 OCT 2020 11:59 |

US3762161

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 11:14:36

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 ☒

US3762161

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 11:14:36

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 06 OCT 2020 09:44 |
| PC Open Date & Time          | 05 OCT 2020 12:00 |
| PC Close Date & Time         | 06 OCT 2020 11:59 |

US3762161

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 11:14:36

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 ☒

US3762161

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 11:14:36

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 06 OCT 2020 21:31 |
| PC Open Date & Time          | 06 OCT 2020 12:00 |
| PC Close Date & Time         | 07 OCT 2020 11:59 |

US3762161

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:14:36

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

07 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3762161

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:14:36

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3762161

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:14:36

Was Contact Attempted?

Yes ☒

No ☐

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

14 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3762161

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:14:36

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3762161

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:14:36

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3762161

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:14:36

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3762161

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:14:36

|                                                                 |                                         |
|-----------------------------------------------------------------|-----------------------------------------|
| Was this visit performed?                                       | Yes <input checked="" type="radio"/>    |
|                                                                 | No <input type="radio"/>                |
| Visit date (dd MMM yyyy)                                        | 03 NOV 2020                             |
| Was visit performed at the participant's home or at the clinic? | Home <input type="radio"/>              |
|                                                                 | Clinic <input checked="" type="radio"/> |
| Folder OID                                                      | VISIT3                                  |

US3762161

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:14:36

|                                           |                                       |
|-------------------------------------------|---------------------------------------|
| Were vital signs assessed?                | Yes <input checked="" type="radio"/>  |
|                                           | No <input type="radio"/>              |
| Date of assessment ( <i>dd MMM yyyy</i> ) | 03 NOV 2020                           |
| Time of assessment ( <i>00:00-23:59</i> ) | 09:41 (24 HR)                         |
| Vital Signs Date and Time (derived)       | 03 NOV 2020 09:41                     |
| Temperature ( <i>xxx.x</i> )              | 97.7 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> )           | 16 breaths/min                        |
| Respiratory Rate units                    | BREATHS/MIN                           |
| Systolic Blood Pressure ( <i>xxx</i> )    | 127 mmHg                              |
| Systolic Blood Pressure units             | MMHG                                  |
| Diastolic Blood Pressure ( <i>xxx</i> )   | 67 mmHg                               |
| Diastolic Blood Pressure units            | MMHG                                  |
| Height (derived)                          |                                       |
| Weight (derived)                          |                                       |

US3762161

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:14:36

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.*

US3762161

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:14:36

Was the sample collected?

Yes ☒

No ☐

Collection date (*dd MMM yyyy*)

03 NOV 2020

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

10:03 (24 HR)

Collection date and time (derived)

03 NOV 2020 10:03

US3762161

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:14:36

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3762161

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:36

**TIMEPOINT**

DAY 64

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

No ☒

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

02 NOV 2020 22:42:24

Patient Cloud Open Date & Time

02 NOV 2020 00:01

Patient Cloud Close Date & Time

06 NOV 2020 23:59

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:36

| 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"/>                                               |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

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

[Patient Cloud Close Date & Time](#)

03 NOV 2020 23:59

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:36

| 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"/>                                               |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

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

[Patient Cloud Close Date & Time](#)

10 NOV 2020 23:59

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:36

| 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"/>                                               |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

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

[Patient Cloud Close Date & Time](#)

17 NOV 2020 23:59

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:36

| 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"/>                                               |



**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

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

[Patient Cloud Close Date & Time](#)

24 NOV 2020 23:59

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:36

| 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"/>                                               |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

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

[Patient Cloud Close Date & Time](#)

01 DEC 2020 23:59

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:36

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

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

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

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08 DEC 2020 23:59

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:36

**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 ☐ 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 ☐

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

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

[Patient Cloud Close Date & Time](#)

15 DEC 2020 23:59

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:36

| 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"/>                                               |



**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

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

[Patient Cloud Close Date & Time](#)

22 DEC 2020 23:59

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:36

| 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"/>                                               |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

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

[Patient Cloud Close Date & Time](#)

29 DEC 2020 23:59

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:36

| 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"/>                                               |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

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

[Patient Cloud Close Date & Time](#)

05 JAN 2021 23:59

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:36

| 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"/>                                               |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

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

[Patient Cloud Close Date & Time](#)

12 JAN 2021 23:59

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:36

| 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"/>                                               |



**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

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

[Patient Cloud Close Date & Time](#)

19 JAN 2021 23:59

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:36

| 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"/>                                               |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

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

[Patient Cloud Close Date & Time](#)

26 JAN 2021 23:59

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:36

| 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"/>                                               |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

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

[Patient Cloud Close Date & Time](#)

02 FEB 2021 23:59

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:36

| 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"/>                                               |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

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

[Patient Cloud Close Date & Time](#)

09 FEB 2021 23:59

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:36

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



**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

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

[Patient Cloud Close Date & Time](#)

16 FEB 2021 23:59

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:36

**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 ☐

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

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

[Patient Cloud Close Date & Time](#)

23 FEB 2021 23:59

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:36

| 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"/>                                               |

**US3762161**

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

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**Generated On: 26 Nov 2020 11:14:36**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

02 MAR 2021 23:59

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:36

| 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"/>                                               |

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

09 MAR 2021 23:59

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:36

| 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"/>                                               |



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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

16 MAR 2021 23:59

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:36

| 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"/>                                               |

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

23 MAR 2021 23:59

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:36

| 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"/>                                               |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

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

[Patient Cloud Close Date & Time](#)

30 MAR 2021 23:59

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:36

| 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"/>                                               |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

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

[Patient Cloud Close Date & Time](#)

06 APR 2021 23:59

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:36

| 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"/>                                               |



**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

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

[Patient Cloud Close Date & Time](#)

13 APR 2021 23:59

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:36

| 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"/>                                               |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

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

[Patient Cloud Close Date & Time](#)

20 APR 2021 23:59

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:36

| 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"/>                                               |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

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

[Patient Cloud Close Date & Time](#)

27 APR 2021 23:59

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:36

| 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"/>                                               |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

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

[Patient Cloud Close Date & Time](#)

04 MAY 2021 23:59

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:36

| 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"/>                                               |



**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

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

[Patient Cloud Close Date & Time](#)

11 MAY 2021 23:59

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:36

| 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"/>                                               |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

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

[Patient Cloud Close Date & Time](#)

18 MAY 2021 23:59

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:36

| 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"/>                                               |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

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

[Patient Cloud Close Date & Time](#)

25 MAY 2021 23:59

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:36

| 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"/>                                               |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

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

[Patient Cloud Close Date & Time](#)

01 JUN 2021 23:59

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:36

| 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"/>                                               |



**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

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

[Patient Cloud Close Date & Time](#)

08 JUN 2021 23:59

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:36

| 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"/>                                               |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

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

[Patient Cloud Close Date & Time](#)

15 JUN 2021 23:59

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:36

| 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"/>                                               |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

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

[Patient Cloud Close Date & Time](#)

22 JUN 2021 23:59

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:36

| 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"/>                                               |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

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

[Patient Cloud Close Date & Time](#)

29 JUN 2021 23:59

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:36

| 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"/>                                               |



**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

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

[Patient Cloud Close Date & Time](#)

06 JUL 2021 23:59

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:36

| 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"/>                                               |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

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

[Patient Cloud Close Date & Time](#)

13 JUL 2021 23:59

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:36

| 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"/>                                               |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

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

[Patient Cloud Close Date & Time](#)

20 JUL 2021 23:59

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:36

| 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"/>                                               |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

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

[Patient Cloud Close Date & Time](#)

27 JUL 2021 23:59

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:36

| 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"/>                                               |



**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

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

[Patient Cloud Close Date & Time](#)

03 AUG 2021 23:59

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:36

| 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"/>                                               |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

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

[Patient Cloud Close Date & Time](#)

10 AUG 2021 23:59

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:36

| 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"/>                                               |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

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

[Patient Cloud Close Date & Time](#)

17 AUG 2021 23:59

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:36

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

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

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

[Patient Cloud Close Date & Time](#)

24 AUG 2021 23:59

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:36

| 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"/>                                               |



**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

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

[Patient Cloud Close Date & Time](#)

31 AUG 2021 23:59

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:36

| 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"/>                                               |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

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

[Patient Cloud Close Date & Time](#)

07 SEP 2021 23:59

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:36

| 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"/>                                               |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

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

[Patient Cloud Close Date & Time](#)

14 SEP 2021 23:59

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:36

TIMEPOINT

DAY 383

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

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

[Patient Cloud Close Date & Time](#)

21 SEP 2021 23:59

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:36

| 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"/>                                               |



**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

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

[Patient Cloud Close Date & Time](#)

28 SEP 2021 23:59

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:36

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 ☐ 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 ☐

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

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

[Patient Cloud Close Date & Time](#)

05 OCT 2021 23:59

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:36

| 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"/>                                               |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

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

[Patient Cloud Close Date & Time](#)

12 OCT 2021 23:59

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:36

| 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"/>                                               |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

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

[Patient Cloud Close Date & Time](#)

19 OCT 2021 23:59

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:36

| 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"/>                                               |



**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

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

[Patient Cloud Close Date & Time](#)

26 OCT 2021 23:59

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:36

| 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"/>                                               |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

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

[Patient Cloud Close Date & Time](#)

02 NOV 2021 23:59

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:36

| 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"/>                                               |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

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

[Patient Cloud Close Date & Time](#)

09 NOV 2021 23:59

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:36

| 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"/>                                               |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

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

[Patient Cloud Close Date & Time](#)

16 NOV 2021 23:59

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:36

| 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"/>                                               |



**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

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

[Patient Cloud Close Date & Time](#)

23 NOV 2021 23:59

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:36

**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 ☐ 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 ☐

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

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

[Patient Cloud Close Date & Time](#)

30 NOV 2021 23:59

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:36

| 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"/>                                               |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

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

[Patient Cloud Close Date & Time](#)

07 DEC 2021 23:59

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:36

| 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"/>                                               |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

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

[Patient Cloud Close Date & Time](#)

14 DEC 2021 23:59

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:36

| 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"/>                                               |



**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

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

[Patient Cloud Close Date & Time](#)

21 DEC 2021 23:59

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:36

| 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"/>                                               |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

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

[Patient Cloud Close Date & Time](#)

28 DEC 2021 23:59

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:36

| 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"/>                                               |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

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

[Patient Cloud Close Date & Time](#)

04 JAN 2022 23:59

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:36

| 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"/>                                               |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

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

[Patient Cloud Close Date & Time](#)

11 JAN 2022 23:59

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:36

**TIMEPOINT**

DAY 502

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

Please contact your study clinic immediately. Click below to confirm that you have read this 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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14 JAN 2022 00:01

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18 JAN 2022 23:59

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:36

TIMEPOINT

DAY 509

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JAN 2022 23:59

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:36

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

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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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01 FEB 2022 23:59

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:36

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 ☐

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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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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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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 ☐ 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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Please contact your study clinic immediately. Click below to confirm that you have read this 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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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:36

| 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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Please contact your study clinic immediately. Click below to confirm that you have read this 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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Folder: New Safety Follow Up Diary (1)

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Generated On: 26 Nov 2020 11:14:36

| 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"/>                                               |

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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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25 FEB 2022 00:01

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01 MAR 2022 23:59

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:36

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

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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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04 MAR 2022 00:01

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08 MAR 2022 23:59

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:36

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 ☐



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

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15 MAR 2022 23:59

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:36

| 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 <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 ☐

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Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:36

**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 ☐

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

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

[Patient Cloud Close Date & Time](#)

29 MAR 2022 23:59

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:36

**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 ☐

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

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

[Patient Cloud Close Date & Time](#)

05 APR 2022 23:59

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:36

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 ☐



**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

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

[Patient Cloud Close Date & Time](#)

12 APR 2022 23:59

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:36

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 ☐

**US3762161**

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

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**Generated On: 26 Nov 2020 11:14:36**

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

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19 APR 2022 23:59

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:36

| 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"/>                                               |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

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

[Patient Cloud Close Date & Time](#)

26 APR 2022 23:59

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:36

| 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"/>                                               |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

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

[Patient Cloud Close Date & Time](#)

03 MAY 2022 23:59

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:36

| 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"/>                                               |



**US3762161**

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

**Form: Safety Follow Up Diary**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

10 MAY 2022 23:59

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:36

| 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"/>                                               |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

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

[Patient Cloud Close Date & Time](#)

17 MAY 2022 23:59

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:36

| 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"/>                                               |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

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

[Patient Cloud Close Date & Time](#)

24 MAY 2022 23:59

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:36

| 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"/>                                               |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

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

[Patient Cloud Close Date & Time](#)

31 MAY 2022 23:59

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:36

| 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"/>                                               |



**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

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

[Patient Cloud Close Date & Time](#)

07 JUN 2022 23:59

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:36

| 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"/>                                               |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

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

[Patient Cloud Close Date & Time](#)

14 JUN 2022 23:59

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:36

| 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"/>                                               |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

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

[Patient Cloud Close Date & Time](#)

21 JUN 2022 23:59

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:36

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 ☐

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

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

[Patient Cloud Close Date & Time](#)

28 JUN 2022 23:59

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:36

| 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"/>                                               |



**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

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

[Patient Cloud Close Date & Time](#)

05 JUL 2022 23:59

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:36

| 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 <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"/>                                               |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

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

[Patient Cloud Close Date & Time](#)

12 JUL 2022 23:59

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:36

| 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"/>                                               |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

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

[Patient Cloud Close Date & Time](#)

19 JUL 2022 23:59

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:36

| 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"/>                                               |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

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

[Patient Cloud Close Date & Time](#)

26 JUL 2022 23:59

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:36

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 ☐



**US3762161**

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**Form: Safety Follow Up Diary**

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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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29 JUL 2022 00:01

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02 AUG 2022 23:59

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:36

| 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 <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 ☐

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05 AUG 2022 00:01

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09 AUG 2022 23:59

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:36

| 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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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 2022 00:01

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16 AUG 2022 23:59

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Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:36

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

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19 AUG 2022 00:01

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23 AUG 2022 23:59

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Generated On: 26 Nov 2020 11:14:36

| 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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Please contact your study clinic immediately. Click below to confirm that you have read this 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 AUG 2022 23:59

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:36

| 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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Please contact your study clinic immediately. Click below to confirm that you have read this 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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06 SEP 2022 23:59

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Generated On: 26 Nov 2020 11:14:36

| 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"/>                                               |

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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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13 SEP 2022 23:59

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:36

| 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"/>                                               |

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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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16 SEP 2022 00:01

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20 SEP 2022 23:59

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:36

| 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"/>                                               |



**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

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

[Patient Cloud Close Date & Time](#)

27 SEP 2022 23:59

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:36

| 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"/>                                               |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

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

[Patient Cloud Close Date & Time](#)

04 OCT 2022 23:59

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:36

| 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"/>                                               |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

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

[Patient Cloud Close Date & Time](#)

11 OCT 2022 23:59

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:36

| 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"/>                                               |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

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

[Patient Cloud Close Date & Time](#)

18 OCT 2022 23:59

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:36

| 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"/>                                               |



**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

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

[Patient Cloud Close Date & Time](#)

25 OCT 2022 23:59

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:36

| 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"/>                                               |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

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

[Patient Cloud Close Date & Time](#)

01 NOV 2022 23:59

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:36

| 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"/>                                               |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

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

[Patient Cloud Close Date & Time](#)

08 NOV 2022 23:59

**US3762161**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 11:14:36**

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*

US3762161

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:14:36

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 11:14:36

|                                                  |                                                               |
|--------------------------------------------------|---------------------------------------------------------------|
| Date of Contact                                  | 9 NOV 2020                                                    |
| Time of Contact                                  | 14:25                                                         |
| Date and Time of Contact (derived)               | 9 NOV 2020 14:25                                              |
| Type of Contact                                  | Clinic Visit - Scheduled <input type="radio"/>                |
|                                                  | Clinical Visit - Unscheduled <input checked="" type="radio"/> |
|                                                  | Safety Call <input type="radio"/>                             |
|                                                  | Convalescent Tele-visit <input type="radio"/>                 |
| Has the subject reported symptoms of SARS-COV-2? | Yes <input checked="" type="radio"/>                          |
|                                                  | No <input type="radio"/>                                      |



US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:14:36

Symptom Day

|        |                                     |
|--------|-------------------------------------|
| Day 1  | <input type="checkbox"/>            |
| Day 2  | <input type="checkbox"/>            |
| Day 3  | <input type="checkbox"/>            |
| Day 4  | <input type="checkbox"/>            |
| Day 5  | <input checked="" type="checkbox"/> |
| Day 6  | <input type="checkbox"/>            |
| Day 7  | <input type="checkbox"/>            |
| Day 8  | <input type="checkbox"/>            |
| Day 9  | <input type="checkbox"/>            |
| Day 10 | <input type="checkbox"/>            |
| Day 11 | <input type="checkbox"/>            |
| Day 12 | <input type="checkbox"/>            |
| Day 13 | <input type="checkbox"/>            |
| Day 14 | <input type="checkbox"/>            |
| Day 15 | <input type="checkbox"/>            |
| Day 16 | <input type="checkbox"/>            |
| Day 17 | <input type="checkbox"/>            |
| Day 18 | <input type="checkbox"/>            |
| Day 19 | <input type="checkbox"/>            |
| Day 20 | <input type="checkbox"/>            |
| Day 21 | <input type="checkbox"/>            |
| Day 22 | <input type="checkbox"/>            |
| Day 23 | <input type="checkbox"/>            |
| Day 24 | <input type="checkbox"/>            |
| Day 25 | <input type="checkbox"/>            |
| Day 26 | <input type="checkbox"/>            |
| Day 27 | <input type="checkbox"/>            |
| Day 28 | <input type="checkbox"/>            |
| Day 29 | <input type="checkbox"/>            |
| Day 30 | <input type="checkbox"/>            |
| Day 31 | <input type="checkbox"/>            |
| Day 32 | <input type="checkbox"/>            |
| Day 33 | <input type="checkbox"/>            |

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:14:36

|                      |             |                                     |
|----------------------|-------------|-------------------------------------|
|                      | Day 34      | <input type="checkbox"/>            |
|                      | Day 35      | <input type="checkbox"/>            |
|                      | Day 36      | <input type="checkbox"/>            |
|                      | Day 37      | <input type="checkbox"/>            |
|                      | Day 38      | <input type="checkbox"/>            |
|                      | Day 39      | <input type="checkbox"/>            |
|                      | Day 40      | <input type="checkbox"/>            |
| Date                 | 9 NOV 2020  |                                     |
| Assessment Not Done  | False       |                                     |
| O2 Saturation        | 95 %        |                                     |
| O2 Saturation Units  | %           |                                     |
| Temperature          | 98.4 F      |                                     |
| Chills               | None        | <input type="checkbox"/>            |
|                      | Mild        | <input type="checkbox"/>            |
|                      | Moderate    | <input checked="" type="checkbox"/> |
|                      | Severe      | <input type="checkbox"/>            |
|                      | Not Done    | <input type="checkbox"/>            |
| Cough                | None        | <input type="checkbox"/>            |
|                      | Mild        | <input checked="" type="checkbox"/> |
|                      | Moderate    | <input type="checkbox"/>            |
|                      | Severe      | <input type="checkbox"/>            |
|                      | Not Done    | <input type="checkbox"/>            |
| Shortness of Breath  | None        | <input checked="" type="checkbox"/> |
|                      | Mild        | <input type="checkbox"/>            |
|                      | Moderate    | <input type="checkbox"/>            |
|                      | Severe      | <input type="checkbox"/>            |
|                      | Not Done    | <input type="checkbox"/>            |
| Difficulty Breathing | None        | <input checked="" type="checkbox"/> |
|                      | Mild        | <input type="checkbox"/>            |
|                      | Moderate    | <input type="checkbox"/>            |
|                      | Severe      | <input type="checkbox"/>            |
|                      | Not Done    | <input type="checkbox"/>            |
| Fatigue              | None        | <input checked="" type="checkbox"/> |
| v6.020 DTW (1102)    | 337 of 2361 |                                     |

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Form: Symptom Log (1)

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|                        |          |                                     |
|------------------------|----------|-------------------------------------|
|                        | Mild     | <input type="checkbox"/>            |
|                        | Moderate | <input type="checkbox"/>            |
|                        | Severe   | <input type="checkbox"/>            |
|                        | Not Done | <input type="checkbox"/>            |
| Muscle Aches (Myalgia) | None     | <input type="checkbox"/>            |
|                        | Mild     | <input type="checkbox"/>            |
|                        | Moderate | <input checked="" type="checkbox"/> |
|                        | Severe   | <input type="checkbox"/>            |
|                        | Not Done | <input type="checkbox"/>            |
| Body Aches             | None     | <input type="checkbox"/>            |
|                        | Mild     | <input type="checkbox"/>            |
|                        | Moderate | <input checked="" type="checkbox"/> |
|                        | Severe   | <input type="checkbox"/>            |
|                        | Not Done | <input type="checkbox"/>            |
| Headache               | None     | <input type="checkbox"/>            |
|                        | Mild     | <input type="checkbox"/>            |
|                        | Moderate | <input type="checkbox"/>            |
|                        | Severe   | <input checked="" type="checkbox"/> |
|                        | Not Done | <input type="checkbox"/>            |
| New Loss of Taste      | None     | <input checked="" type="checkbox"/> |
|                        | Mild     | <input type="checkbox"/>            |
|                        | Moderate | <input type="checkbox"/>            |
|                        | Severe   | <input type="checkbox"/>            |
|                        | Not Done | <input type="checkbox"/>            |
| New Loss of Smell      | None     | <input checked="" type="checkbox"/> |
|                        | Mild     | <input type="checkbox"/>            |
|                        | Moderate | <input type="checkbox"/>            |
|                        | Severe   | <input type="checkbox"/>            |
|                        | Not Done | <input type="checkbox"/>            |
| Nasal Congestion       | None     | <input checked="" type="checkbox"/> |
|                        | Mild     | <input type="checkbox"/>            |
|                        | Moderate | <input type="checkbox"/>            |

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Form: Symptom Log (1)

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|                         |          |                                     |
|-------------------------|----------|-------------------------------------|
|                         | Severe   | <input type="checkbox"/>            |
|                         | Not Done | <input type="checkbox"/>            |
| Runny Nose (Rhinorrhea) | None     | <input checked="" type="checkbox"/> |
|                         | Mild     | <input type="checkbox"/>            |
|                         | Moderate | <input type="checkbox"/>            |
|                         | Severe   | <input type="checkbox"/>            |
|                         | Not Done | <input type="checkbox"/>            |
| Nausea                  | None     | <input checked="" type="checkbox"/> |
|                         | Mild     | <input type="checkbox"/>            |
|                         | Moderate | <input type="checkbox"/>            |
|                         | Severe   | <input type="checkbox"/>            |
|                         | Not Done | <input type="checkbox"/>            |
| Vomiting                | None     | <input checked="" type="checkbox"/> |
|                         | Mild     | <input type="checkbox"/>            |
|                         | Moderate | <input type="checkbox"/>            |
|                         | Severe   | <input type="checkbox"/>            |
|                         | Not Done | <input type="checkbox"/>            |
| Diarrhea                | None     | <input checked="" type="checkbox"/> |
|                         | Mild     | <input type="checkbox"/>            |
|                         | Moderate | <input type="checkbox"/>            |
|                         | Severe   | <input type="checkbox"/>            |
|                         | Not Done | <input type="checkbox"/>            |
| Sore Throat             | None     | <input type="checkbox"/>            |
|                         | Mild     | <input checked="" type="checkbox"/> |
|                         | Moderate | <input type="checkbox"/>            |
|                         | Severe   | <input type="checkbox"/>            |
|                         | Not Done | <input type="checkbox"/>            |

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Form: Symptom Log (2)

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Symptom Day

|        |                                     |
|--------|-------------------------------------|
| Day 1  | <input checked="" type="checkbox"/> |
| Day 2  | <input type="checkbox"/>            |
| Day 3  | <input type="checkbox"/>            |
| Day 4  | <input type="checkbox"/>            |
| Day 5  | <input type="checkbox"/>            |
| Day 6  | <input type="checkbox"/>            |
| Day 7  | <input type="checkbox"/>            |
| Day 8  | <input type="checkbox"/>            |
| Day 9  | <input type="checkbox"/>            |
| Day 10 | <input type="checkbox"/>            |
| Day 11 | <input type="checkbox"/>            |
| Day 12 | <input type="checkbox"/>            |
| Day 13 | <input type="checkbox"/>            |
| Day 14 | <input type="checkbox"/>            |
| Day 15 | <input type="checkbox"/>            |
| Day 16 | <input type="checkbox"/>            |
| Day 17 | <input type="checkbox"/>            |
| Day 18 | <input type="checkbox"/>            |
| Day 19 | <input type="checkbox"/>            |
| Day 20 | <input type="checkbox"/>            |
| Day 21 | <input type="checkbox"/>            |
| Day 22 | <input type="checkbox"/>            |
| Day 23 | <input type="checkbox"/>            |
| Day 24 | <input type="checkbox"/>            |
| Day 25 | <input type="checkbox"/>            |
| Day 26 | <input type="checkbox"/>            |
| Day 27 | <input type="checkbox"/>            |
| Day 28 | <input type="checkbox"/>            |
| Day 29 | <input type="checkbox"/>            |
| Day 30 | <input type="checkbox"/>            |
| Day 31 | <input type="checkbox"/>            |
| Day 32 | <input type="checkbox"/>            |
| Day 33 | <input type="checkbox"/>            |

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Form: Symptom Log (2)

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|                      |               |                                  |
|----------------------|---------------|----------------------------------|
|                      | Day 34        | <input type="checkbox"/>         |
|                      | Day 35        | <input type="checkbox"/>         |
|                      | Day 36        | <input type="checkbox"/>         |
|                      | Day 37        | <input type="checkbox"/>         |
|                      | Day 38        | <input type="checkbox"/>         |
|                      | Day 39        | <input type="checkbox"/>         |
|                      | Day 40        | <input type="checkbox"/>         |
| Date                 | 05 NOV 2020   |                                  |
| Assessment Not Done  | False         |                                  |
| O2 Saturation        | ND - Not Done |                                  |
| O2 Saturation Units  | %             |                                  |
| Temperature          | ND - Not Done |                                  |
| Chills               | None          | <input checked="" type="radio"/> |
|                      | Mild          | <input type="radio"/>            |
|                      | Moderate      | <input type="radio"/>            |
|                      | Severe        | <input type="radio"/>            |
|                      | Not Done      | <input type="radio"/>            |
| Cough                | None          | <input checked="" type="radio"/> |
|                      | Mild          | <input type="radio"/>            |
|                      | Moderate      | <input type="radio"/>            |
|                      | Severe        | <input type="radio"/>            |
|                      | Not Done      | <input type="radio"/>            |
| Shortness of Breath  | None          | <input checked="" type="radio"/> |
|                      | Mild          | <input type="radio"/>            |
|                      | Moderate      | <input type="radio"/>            |
|                      | Severe        | <input type="radio"/>            |
|                      | Not Done      | <input type="radio"/>            |
| Difficulty Breathing | None          | <input checked="" type="radio"/> |
|                      | Mild          | <input type="radio"/>            |
|                      | Moderate      | <input type="radio"/>            |
|                      | Severe        | <input type="radio"/>            |
|                      | Not Done      | <input type="radio"/>            |
| Fatigue              | None          | <input type="radio"/>            |
| v6.020 DTW (1102)    | 341 of 2361   |                                  |

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Form: Symptom Log (2)

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|                        |          |                                  |
|------------------------|----------|----------------------------------|
|                        | Mild     | <input checked="" type="radio"/> |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |
| Muscle Aches (Myalgia) | None     | <input checked="" type="radio"/> |
|                        | Mild     | <input type="radio"/>            |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |
| Body Aches             | None     | <input checked="" type="radio"/> |
|                        | Mild     | <input type="radio"/>            |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |
| Headache               | None     | <input type="radio"/>            |
|                        | Mild     | <input type="radio"/>            |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input checked="" type="radio"/> |
|                        | Not Done | <input type="radio"/>            |
| New Loss of Taste      | None     | <input checked="" type="radio"/> |
|                        | Mild     | <input type="radio"/>            |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |
| New Loss of Smell      | None     | <input checked="" type="radio"/> |
|                        | Mild     | <input type="radio"/>            |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |
| Nasal Congestion       | None     | <input checked="" type="radio"/> |
|                        | Mild     | <input type="radio"/>            |
|                        | Moderate | <input type="radio"/>            |

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Form: Symptom Log (2)

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|                         |          |                                     |
|-------------------------|----------|-------------------------------------|
|                         | Severe   | <input type="checkbox"/>            |
|                         | Not Done | <input type="checkbox"/>            |
| Runny Nose (Rhinorrhea) | None     | <input checked="" type="checkbox"/> |
|                         | Mild     | <input type="checkbox"/>            |
|                         | Moderate | <input type="checkbox"/>            |
|                         | Severe   | <input type="checkbox"/>            |
|                         | Not Done | <input type="checkbox"/>            |
| Nausea                  | None     | <input checked="" type="checkbox"/> |
|                         | Mild     | <input type="checkbox"/>            |
|                         | Moderate | <input type="checkbox"/>            |
|                         | Severe   | <input type="checkbox"/>            |
|                         | Not Done | <input type="checkbox"/>            |
| Vomiting                | None     | <input checked="" type="checkbox"/> |
|                         | Mild     | <input type="checkbox"/>            |
|                         | Moderate | <input type="checkbox"/>            |
|                         | Severe   | <input type="checkbox"/>            |
|                         | Not Done | <input type="checkbox"/>            |
| Diarrhea                | None     | <input type="checkbox"/>            |
|                         | Mild     | <input checked="" type="checkbox"/> |
|                         | Moderate | <input type="checkbox"/>            |
|                         | Severe   | <input type="checkbox"/>            |
|                         | Not Done | <input type="checkbox"/>            |
| Sore Throat             | None     | <input checked="" type="checkbox"/> |
|                         | Mild     | <input type="checkbox"/>            |
|                         | Moderate | <input type="checkbox"/>            |
|                         | Severe   | <input type="checkbox"/>            |
|                         | Not Done | <input type="checkbox"/>            |



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Form: Symptom Log (3)

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Symptom Day

|        |                                     |
|--------|-------------------------------------|
| Day 1  | <input type="checkbox"/>            |
| Day 2  | <input checked="" type="checkbox"/> |
| Day 3  | <input type="checkbox"/>            |
| Day 4  | <input type="checkbox"/>            |
| Day 5  | <input type="checkbox"/>            |
| Day 6  | <input type="checkbox"/>            |
| Day 7  | <input type="checkbox"/>            |
| Day 8  | <input type="checkbox"/>            |
| Day 9  | <input type="checkbox"/>            |
| Day 10 | <input type="checkbox"/>            |
| Day 11 | <input type="checkbox"/>            |
| Day 12 | <input type="checkbox"/>            |
| Day 13 | <input type="checkbox"/>            |
| Day 14 | <input type="checkbox"/>            |
| Day 15 | <input type="checkbox"/>            |
| Day 16 | <input type="checkbox"/>            |
| Day 17 | <input type="checkbox"/>            |
| Day 18 | <input type="checkbox"/>            |
| Day 19 | <input type="checkbox"/>            |
| Day 20 | <input type="checkbox"/>            |
| Day 21 | <input type="checkbox"/>            |
| Day 22 | <input type="checkbox"/>            |
| Day 23 | <input type="checkbox"/>            |
| Day 24 | <input type="checkbox"/>            |
| Day 25 | <input type="checkbox"/>            |
| Day 26 | <input type="checkbox"/>            |
| Day 27 | <input type="checkbox"/>            |
| Day 28 | <input type="checkbox"/>            |
| Day 29 | <input type="checkbox"/>            |
| Day 30 | <input type="checkbox"/>            |
| Day 31 | <input type="checkbox"/>            |
| Day 32 | <input type="checkbox"/>            |
| Day 33 | <input type="checkbox"/>            |

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Form: Symptom Log (3)

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|                      |               |                                  |
|----------------------|---------------|----------------------------------|
|                      | Day 34        | <input type="checkbox"/>         |
|                      | Day 35        | <input type="checkbox"/>         |
|                      | Day 36        | <input type="checkbox"/>         |
|                      | Day 37        | <input type="checkbox"/>         |
|                      | Day 38        | <input type="checkbox"/>         |
|                      | Day 39        | <input type="checkbox"/>         |
|                      | Day 40        | <input type="checkbox"/>         |
| Date                 | 06 NOV 2020   |                                  |
| Assessment Not Done  | False         |                                  |
| O2 Saturation        | ND - Not Done |                                  |
| O2 Saturation Units  | %             |                                  |
| Temperature          | ND - Not Done |                                  |
| Chills               | None          | <input checked="" type="radio"/> |
|                      | Mild          | <input type="radio"/>            |
|                      | Moderate      | <input type="radio"/>            |
|                      | Severe        | <input type="radio"/>            |
|                      | Not Done      | <input type="radio"/>            |
| Cough                | None          | <input checked="" type="radio"/> |
|                      | Mild          | <input type="radio"/>            |
|                      | Moderate      | <input type="radio"/>            |
|                      | Severe        | <input type="radio"/>            |
|                      | Not Done      | <input type="radio"/>            |
| Shortness of Breath  | None          | <input checked="" type="radio"/> |
|                      | Mild          | <input type="radio"/>            |
|                      | Moderate      | <input type="radio"/>            |
|                      | Severe        | <input type="radio"/>            |
|                      | Not Done      | <input type="radio"/>            |
| Difficulty Breathing | None          | <input checked="" type="radio"/> |
|                      | Mild          | <input type="radio"/>            |
|                      | Moderate      | <input type="radio"/>            |
|                      | Severe        | <input type="radio"/>            |
|                      | Not Done      | <input type="radio"/>            |
| Fatigue              | None          | <input type="radio"/>            |
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Form: Symptom Log (3)

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|                        |          |                                  |
|------------------------|----------|----------------------------------|
|                        | Mild     | <input type="radio"/>            |
|                        | Moderate | <input checked="" type="radio"/> |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |
| Muscle Aches (Myalgia) | None     | <input checked="" type="radio"/> |
|                        | Mild     | <input type="radio"/>            |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |
| Body Aches             | None     | <input checked="" type="radio"/> |
|                        | Mild     | <input type="radio"/>            |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |
| Headache               | None     | <input type="radio"/>            |
|                        | Mild     | <input type="radio"/>            |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input checked="" type="radio"/> |
|                        | Not Done | <input type="radio"/>            |
| New Loss of Taste      | None     | <input checked="" type="radio"/> |
|                        | Mild     | <input type="radio"/>            |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |
| New Loss of Smell      | None     | <input checked="" type="radio"/> |
|                        | Mild     | <input type="radio"/>            |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |
| Nasal Congestion       | None     | <input checked="" type="radio"/> |
|                        | Mild     | <input type="radio"/>            |
|                        | Moderate | <input type="radio"/>            |

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Form: Symptom Log (3)

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|                         |          |                                     |
|-------------------------|----------|-------------------------------------|
|                         | Severe   | <input type="checkbox"/>            |
|                         | Not Done | <input type="checkbox"/>            |
| Runny Nose (Rhinorrhea) | None     | <input checked="" type="checkbox"/> |
|                         | Mild     | <input type="checkbox"/>            |
|                         | Moderate | <input type="checkbox"/>            |
|                         | Severe   | <input type="checkbox"/>            |
|                         | Not Done | <input type="checkbox"/>            |
| Nausea                  | None     | <input checked="" type="checkbox"/> |
|                         | Mild     | <input type="checkbox"/>            |
|                         | Moderate | <input type="checkbox"/>            |
|                         | Severe   | <input type="checkbox"/>            |
|                         | Not Done | <input type="checkbox"/>            |
| Vomiting                | None     | <input checked="" type="checkbox"/> |
|                         | Mild     | <input type="checkbox"/>            |
|                         | Moderate | <input type="checkbox"/>            |
|                         | Severe   | <input type="checkbox"/>            |
|                         | Not Done | <input type="checkbox"/>            |
| Diarrhea                | None     | <input checked="" type="checkbox"/> |
|                         | Mild     | <input type="checkbox"/>            |
|                         | Moderate | <input type="checkbox"/>            |
|                         | Severe   | <input type="checkbox"/>            |
|                         | Not Done | <input type="checkbox"/>            |
| Sore Throat             | None     | <input type="checkbox"/>            |
|                         | Mild     | <input checked="" type="checkbox"/> |
|                         | Moderate | <input type="checkbox"/>            |
|                         | Severe   | <input type="checkbox"/>            |
|                         | Not Done | <input type="checkbox"/>            |

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Form: Symptom Log (4)

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Symptom Day

|        |                                     |
|--------|-------------------------------------|
| Day 1  | <input type="checkbox"/>            |
| Day 2  | <input type="checkbox"/>            |
| Day 3  | <input checked="" type="checkbox"/> |
| Day 4  | <input type="checkbox"/>            |
| Day 5  | <input type="checkbox"/>            |
| Day 6  | <input type="checkbox"/>            |
| Day 7  | <input type="checkbox"/>            |
| Day 8  | <input type="checkbox"/>            |
| Day 9  | <input type="checkbox"/>            |
| Day 10 | <input type="checkbox"/>            |
| Day 11 | <input type="checkbox"/>            |
| Day 12 | <input type="checkbox"/>            |
| Day 13 | <input type="checkbox"/>            |
| Day 14 | <input type="checkbox"/>            |
| Day 15 | <input type="checkbox"/>            |
| Day 16 | <input type="checkbox"/>            |
| Day 17 | <input type="checkbox"/>            |
| Day 18 | <input type="checkbox"/>            |
| Day 19 | <input type="checkbox"/>            |
| Day 20 | <input type="checkbox"/>            |
| Day 21 | <input type="checkbox"/>            |
| Day 22 | <input type="checkbox"/>            |
| Day 23 | <input type="checkbox"/>            |
| Day 24 | <input type="checkbox"/>            |
| Day 25 | <input type="checkbox"/>            |
| Day 26 | <input type="checkbox"/>            |
| Day 27 | <input type="checkbox"/>            |
| Day 28 | <input type="checkbox"/>            |
| Day 29 | <input type="checkbox"/>            |
| Day 30 | <input type="checkbox"/>            |
| Day 31 | <input type="checkbox"/>            |
| Day 32 | <input type="checkbox"/>            |
| Day 33 | <input type="checkbox"/>            |

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Form: Symptom Log (4)

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|                      |               |                                  |
|----------------------|---------------|----------------------------------|
|                      | Day 34        | <input type="checkbox"/>         |
|                      | Day 35        | <input type="checkbox"/>         |
|                      | Day 36        | <input type="checkbox"/>         |
|                      | Day 37        | <input type="checkbox"/>         |
|                      | Day 38        | <input type="checkbox"/>         |
|                      | Day 39        | <input type="checkbox"/>         |
|                      | Day 40        | <input type="checkbox"/>         |
| Date                 | 07 NOV 2020   |                                  |
| Assessment Not Done  | False         |                                  |
| O2 Saturation        | ND - Not Done |                                  |
| O2 Saturation Units  | %             |                                  |
| Temperature          | ND - Not Done |                                  |
| Chills               | None          | <input checked="" type="radio"/> |
|                      | Mild          | <input type="radio"/>            |
|                      | Moderate      | <input type="radio"/>            |
|                      | Severe        | <input type="radio"/>            |
|                      | Not Done      | <input type="radio"/>            |
| Cough                | None          | <input checked="" type="radio"/> |
|                      | Mild          | <input type="radio"/>            |
|                      | Moderate      | <input type="radio"/>            |
|                      | Severe        | <input type="radio"/>            |
|                      | Not Done      | <input type="radio"/>            |
| Shortness of Breath  | None          | <input checked="" type="radio"/> |
|                      | Mild          | <input type="radio"/>            |
|                      | Moderate      | <input type="radio"/>            |
|                      | Severe        | <input type="radio"/>            |
|                      | Not Done      | <input type="radio"/>            |
| Difficulty Breathing | None          | <input checked="" type="radio"/> |
|                      | Mild          | <input type="radio"/>            |
|                      | Moderate      | <input type="radio"/>            |
|                      | Severe        | <input type="radio"/>            |
|                      | Not Done      | <input type="radio"/>            |
| Fatigue              | None          | <input type="radio"/>            |
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Form: Symptom Log (4)

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|                        |          |                                  |
|------------------------|----------|----------------------------------|
|                        | Mild     | <input type="radio"/>            |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input checked="" type="radio"/> |
|                        | Not Done | <input type="radio"/>            |
| Muscle Aches (Myalgia) | None     | <input checked="" type="radio"/> |
|                        | Mild     | <input type="radio"/>            |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |
| Body Aches             | None     | <input checked="" type="radio"/> |
|                        | Mild     | <input type="radio"/>            |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |
| Headache               | None     | <input type="radio"/>            |
|                        | Mild     | <input type="radio"/>            |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input checked="" type="radio"/> |
|                        | Not Done | <input type="radio"/>            |
| New Loss of Taste      | None     | <input checked="" type="radio"/> |
|                        | Mild     | <input type="radio"/>            |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |
| New Loss of Smell      | None     | <input checked="" type="radio"/> |
|                        | Mild     | <input type="radio"/>            |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |
| Nasal Congestion       | None     | <input checked="" type="radio"/> |
|                        | Mild     | <input type="radio"/>            |
|                        | Moderate | <input type="radio"/>            |

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Form: Symptom Log (4)

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|                         |          |                                     |
|-------------------------|----------|-------------------------------------|
|                         | Severe   | <input type="checkbox"/>            |
|                         | Not Done | <input type="checkbox"/>            |
| Runny Nose (Rhinorrhea) | None     | <input checked="" type="checkbox"/> |
|                         | Mild     | <input type="checkbox"/>            |
|                         | Moderate | <input type="checkbox"/>            |
|                         | Severe   | <input type="checkbox"/>            |
|                         | Not Done | <input type="checkbox"/>            |
| Nausea                  | None     | <input checked="" type="checkbox"/> |
|                         | Mild     | <input type="checkbox"/>            |
|                         | Moderate | <input type="checkbox"/>            |
|                         | Severe   | <input type="checkbox"/>            |
|                         | Not Done | <input type="checkbox"/>            |
| Vomiting                | None     | <input checked="" type="checkbox"/> |
|                         | Mild     | <input type="checkbox"/>            |
|                         | Moderate | <input type="checkbox"/>            |
|                         | Severe   | <input type="checkbox"/>            |
|                         | Not Done | <input type="checkbox"/>            |
| Diarrhea                | None     | <input checked="" type="checkbox"/> |
|                         | Mild     | <input type="checkbox"/>            |
|                         | Moderate | <input type="checkbox"/>            |
|                         | Severe   | <input type="checkbox"/>            |
|                         | Not Done | <input type="checkbox"/>            |
| Sore Throat             | None     | <input type="checkbox"/>            |
|                         | Mild     | <input type="checkbox"/>            |
|                         | Moderate | <input checked="" type="checkbox"/> |
|                         | Severe   | <input type="checkbox"/>            |
|                         | Not Done | <input type="checkbox"/>            |



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Form: Symptom Log (5)

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[Symptom Day](#)

|        |                                     |
|--------|-------------------------------------|
| Day 1  | <input type="checkbox"/>            |
| Day 2  | <input type="checkbox"/>            |
| Day 3  | <input type="checkbox"/>            |
| Day 4  | <input checked="" type="checkbox"/> |
| Day 5  | <input type="checkbox"/>            |
| Day 6  | <input type="checkbox"/>            |
| Day 7  | <input type="checkbox"/>            |
| Day 8  | <input type="checkbox"/>            |
| Day 9  | <input type="checkbox"/>            |
| Day 10 | <input type="checkbox"/>            |
| Day 11 | <input type="checkbox"/>            |
| Day 12 | <input type="checkbox"/>            |
| Day 13 | <input type="checkbox"/>            |
| Day 14 | <input type="checkbox"/>            |
| Day 15 | <input type="checkbox"/>            |
| Day 16 | <input type="checkbox"/>            |
| Day 17 | <input type="checkbox"/>            |
| Day 18 | <input type="checkbox"/>            |
| Day 19 | <input type="checkbox"/>            |
| Day 20 | <input type="checkbox"/>            |
| Day 21 | <input type="checkbox"/>            |
| Day 22 | <input type="checkbox"/>            |
| Day 23 | <input type="checkbox"/>            |
| Day 24 | <input type="checkbox"/>            |
| Day 25 | <input type="checkbox"/>            |
| Day 26 | <input type="checkbox"/>            |
| Day 27 | <input type="checkbox"/>            |
| Day 28 | <input type="checkbox"/>            |
| Day 29 | <input type="checkbox"/>            |
| Day 30 | <input type="checkbox"/>            |
| Day 31 | <input type="checkbox"/>            |
| Day 32 | <input type="checkbox"/>            |
| Day 33 | <input type="checkbox"/>            |

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:14:36

|                      |               |                                  |
|----------------------|---------------|----------------------------------|
|                      | Day 34        | <input type="checkbox"/>         |
|                      | Day 35        | <input type="checkbox"/>         |
|                      | Day 36        | <input type="checkbox"/>         |
|                      | Day 37        | <input type="checkbox"/>         |
|                      | Day 38        | <input type="checkbox"/>         |
|                      | Day 39        | <input type="checkbox"/>         |
|                      | Day 40        | <input type="checkbox"/>         |
| Date                 | 08 NOV 2020   |                                  |
| Assessment Not Done  | False         |                                  |
| O2 Saturation        | ND - Not Done |                                  |
| O2 Saturation Units  | %             |                                  |
| Temperature          | ND - Not Done |                                  |
| Chills               | None          | <input checked="" type="radio"/> |
|                      | Mild          | <input type="radio"/>            |
|                      | Moderate      | <input type="radio"/>            |
|                      | Severe        | <input type="radio"/>            |
|                      | Not Done      | <input type="radio"/>            |
| Cough                | None          | <input checked="" type="radio"/> |
|                      | Mild          | <input type="radio"/>            |
|                      | Moderate      | <input type="radio"/>            |
|                      | Severe        | <input type="radio"/>            |
|                      | Not Done      | <input type="radio"/>            |
| Shortness of Breath  | None          | <input checked="" type="radio"/> |
|                      | Mild          | <input type="radio"/>            |
|                      | Moderate      | <input type="radio"/>            |
|                      | Severe        | <input type="radio"/>            |
|                      | Not Done      | <input type="radio"/>            |
| Difficulty Breathing | None          | <input checked="" type="radio"/> |
|                      | Mild          | <input type="radio"/>            |
|                      | Moderate      | <input type="radio"/>            |
|                      | Severe        | <input type="radio"/>            |
|                      | Not Done      | <input type="radio"/>            |
| Fatigue              | None          | <input type="radio"/>            |
| v6.020 DTW (1102)    | 353 of 2361   |                                  |

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:14:36

|                        |          |                                  |
|------------------------|----------|----------------------------------|
|                        | Mild     | <input type="radio"/>            |
|                        | Moderate | <input checked="" type="radio"/> |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |
| Muscle Aches (Myalgia) | None     | <input checked="" type="radio"/> |
|                        | Mild     | <input type="radio"/>            |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |
| Body Aches             | None     | <input checked="" type="radio"/> |
|                        | Mild     | <input type="radio"/>            |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |
| Headache               | None     | <input type="radio"/>            |
|                        | Mild     | <input type="radio"/>            |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input checked="" type="radio"/> |
|                        | Not Done | <input type="radio"/>            |
| New Loss of Taste      | None     | <input checked="" type="radio"/> |
|                        | Mild     | <input type="radio"/>            |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |
| New Loss of Smell      | None     | <input checked="" type="radio"/> |
|                        | Mild     | <input type="radio"/>            |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |
| Nasal Congestion       | None     | <input checked="" type="radio"/> |
|                        | Mild     | <input type="radio"/>            |
|                        | Moderate | <input type="radio"/>            |

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:14:36

|                         |          |                                  |
|-------------------------|----------|----------------------------------|
|                         | Severe   | <input type="checkbox"/>         |
|                         | Not Done | <input type="checkbox"/>         |
| Runny Nose (Rhinorrhea) | None     | <input checked="" type="radio"/> |
|                         | Mild     | <input type="radio"/>            |
|                         | Moderate | <input type="radio"/>            |
|                         | Severe   | <input type="radio"/>            |
|                         | Not Done | <input type="radio"/>            |
| Nausea                  | None     | <input checked="" type="radio"/> |
|                         | Mild     | <input type="radio"/>            |
|                         | Moderate | <input type="radio"/>            |
|                         | Severe   | <input type="radio"/>            |
|                         | Not Done | <input type="radio"/>            |
| Vomiting                | None     | <input checked="" type="radio"/> |
|                         | Mild     | <input type="radio"/>            |
|                         | Moderate | <input type="radio"/>            |
|                         | Severe   | <input type="radio"/>            |
|                         | Not Done | <input type="radio"/>            |
| Diarrhea                | None     | <input type="radio"/>            |
|                         | Mild     | <input type="radio"/>            |
|                         | Moderate | <input checked="" type="radio"/> |
|                         | Severe   | <input type="radio"/>            |
|                         | Not Done | <input type="radio"/>            |
| Sore Throat             | None     | <input checked="" type="radio"/> |
|                         | Mild     | <input type="radio"/>            |
|                         | Moderate | <input type="radio"/>            |
|                         | Severe   | <input type="radio"/>            |
|                         | Not Done | <input type="radio"/>            |

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 11:14:36

|                                                                               |                                                                                                                                                              |
|-------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Date of Visit                                                                 | 9 NOV 2020                                                                                                                                                   |
| Was the Subject Tested For SARS-CoV-2 by RT-PCR?                              | Yes <input checked="" type="radio"/><br>No <input type="radio"/>                                                                                             |
| Did Subject Test Positive For SARS-CoV-2 by RT-PCR?                           | Yes <input type="radio"/><br>No <input checked="" type="radio"/>                                                                                             |
| Date of Test                                                                  | 9 NOV 2020                                                                                                                                                   |
| Type of Test Performed                                                        | Nasopharyngeal Swab <input checked="" type="radio"/><br>Nasal Swab <input type="radio"/><br>Saliva Test <input type="radio"/><br>Other <input type="radio"/> |
| Other, specify _____                                                          |                                                                                                                                                              |
| Was this diagnostic test performed at a lab other than the Study Central Lab? | Yes <input type="radio"/><br>No <input checked="" type="radio"/>                                                                                             |
| If yes, provide lab information below                                         |                                                                                                                                                              |
| Lab/ Institution Test Performed                                               | _____                                                                                                                                                        |
| CLIA Certified?                                                               | Yes <input type="radio"/><br>No <input type="radio"/>                                                                                                        |
| COVID-19 Positive (CSA Programming Field Only)                                | 0                                                                                                                                                            |

**US3762161**

**Folder: Covid-19 Assessment 09 Nov 2020**

**Form: Generate Next COVID-19 Assessment**

**Generated On: 26 Nov 2020 11:14:36**

---

Generate Next COVID-19 Assessment

Yes ☐

No ☐

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US3762161

Folder: Illness Visit (1)

Form: Saliva Collection

Generated On: 26 Nov 2020 11:14:36

| Visit  | Was Saliva Collected?  | Date of Collection |
|--------|------------------------|--------------------|
| Day 3  | NA (COVID-19 Negative) |                    |
| Day 5  | NA (COVID-19 Negative) |                    |
| Day 7  | NA (COVID-19 Negative) |                    |
| Day 9  | NA (COVID-19 Negative) |                    |
| Day 14 | NA (COVID-19 Negative) |                    |
| Day 21 | NA (COVID-19 Negative) |                    |
| Day 28 | NA (COVID-19 Negative) |                    |

US3762161

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:14:36

|                                                                 |                                         |
|-----------------------------------------------------------------|-----------------------------------------|
| Was this visit performed?                                       | Yes <input checked="" type="radio"/>    |
|                                                                 | No <input type="radio"/>                |
| Visit date (dd MMM yyyy)                                        | 09 NOV 2020                             |
| Was visit performed at the participant's home or at the clinic? | Home <input type="radio"/>              |
|                                                                 | Clinic <input checked="" type="radio"/> |
| Folder OID                                                      | SICKD1                                  |



US3762161

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:14:36

|                                           |                                       |
|-------------------------------------------|---------------------------------------|
| Were vital signs assessed?                | Yes <input checked="" type="radio"/>  |
|                                           | No <input type="radio"/>              |
| Date of assessment ( <i>dd MMM yyyy</i> ) | 09 NOV 2020                           |
| Time of assessment ( <i>00:00-23:59</i> ) | 14:30 (24 HR)                         |
| Vital Signs Date and Time (derived)       | 09 NOV 2020 14:30                     |
| Height ( <i>xxx.x</i> )                   | ND - Not Done                         |
| Weight ( <i>xxx.x</i> )                   | ND - Not Done                         |
| Temperature ( <i>xxx.x</i> )              | 98.4 F                                |
| Route of measurement                      | Oral <input checked="" type="radio"/> |
|                                           | Axillary <input type="radio"/>        |
|                                           | Other <input type="radio"/>           |
| If Other, specify                         |                                       |
| Pulse ( <i>xxx</i> )                      | 88 beats/min                          |
| Pulse units                               | BPM                                   |
| Respiratory Rate ( <i>xxx</i> )           | 16 breaths/min                        |
| Respiratory Rate units                    | BREATHS/MIN                           |
| Systolic Blood Pressure ( <i>xxx</i> )    | 137 mmHg                              |
| Systolic Blood Pressure units             | MMHG                                  |
| Diastolic Blood Pressure ( <i>xxx</i> )   | 78 mmHg                               |
| Diastolic Blood Pressure units            | MMHG                                  |
| Height (derived)                          |                                       |
| Weight (derived)                          |                                       |

US3762161

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:14:36

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

09 NOV 2020

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

US3762161

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 26 Nov 2020 11:14:36

Was Blood Sample Taken for Immunologic Assessment of  
SARS\_COV-2 Infection?

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

09 NOV 2020

**US3762161**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Visit Date**

**Generated On: 26 Nov 2020 11:14:36**

Was this visit performed? Yes ☐  
No ☐

Visit date (dd MMM yyyy) \_\_\_\_\_

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

Folder OID \_\_\_\_\_

US3762161

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:14:36

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

US3762161

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:14:36

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.*

**US3762161**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection**

**Generated On: 26 Nov 2020 11:14:36**

Was Blood Sample Taken for Immunologic Assessment of  
SARS\_COV-2 Infection?

Yes ☐

No ☐

NA (COVID-19 Negative) ☐

Date of Collection \_\_\_\_\_

US3762161

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 11:14:36

---

Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

---



US3762161

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:14:36

|                                                                |                                                                                                                                                                  |
|----------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| AEID                                                           | USA-US130-2020-MRNA-1273-P30                                                                                                                                     |
|                                                                | 1000001                                                                                                                                                          |
| Adverse event                                                  | SEPSIS                                                                                                                                                           |
| 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)                                       | 10 NOV 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 checked="" type="radio"/><br>Grade 4 <input type="radio"/> |
| Is the adverse event serious?                                  | Yes <input checked="" type="radio"/><br>No <input type="radio"/>                                                                                                 |
| AE is serious due To (check all that apply)                    |                                                                                                                                                                  |
| Death                                                          | False                                                                                                                                                            |
| Life threatening                                               | True                                                                                                                                                             |
| Requires inpatient or prolongation of existing Hospitalization | True                                                                                                                                                             |
| Hospital Admission Date (dd MMM yyyy)                          | 10 NOV 2020                                                                                                                                                      |
| Hospital Discharge Date (dd MMM yyyy)                          | 15 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)                                              | 368 of 2361                                                                                                                                                      |

US3762161

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:14:36

|                                                                              |                                                                                                                                                                                                                                                                                 |
|------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 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                                                        | False                                                                                                                                                                                                                                                                           |
| Outcome                                                                      | Fatal <input type="radio"/><br>Not Recovered/Not Resolved <input checked="" type="radio"/><br>Recovered/Resolved <input type="radio"/><br>Recovered/Resolved with Sequelae <input type="radio"/><br>Recovering/Resolving <input type="radio"/><br>Unknown <input type="radio"/> |
| If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: |                                                                                                                                                                                                                                                                                 |
| Narrative                                                                    |                                                                                                                                                                                                                                                                                 |

US3762161

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:14:36

74 Y/O MALE WHO RECEIVED  
SECOND DOSE OF PRODUCT ON  
9/30 WITHOUT INCIDENT AND  
WAS SEEN FOR ROUTINE F/U  
ON 11/03 AND REPORTED NO  
SYMPTOMS WHO WAS  
ADMITTED TO WFBMC ON 11/10  
WITH DIAGNOSIS OF  
GASTROENTERITIS WITH  
ASSOCIATED SEPSIS, ACUTE  
KIDNEY INJURY, AND  
POSSIBLE GI BLEED. HE HAD  
REPORTED FEELING TIRED  
WITH HEADACHES AND  
MUSCLE ACHES ON 11/09 AND  
WAS SEEN FOR A SICK VISIT. A  
PCR FOR COVID-19 WAS  
PERFORMED AT THE TIME WAS  
NEGATIVE. ON TELEPHONE F/U  
ON 11/10, HE REPORTED  
INCREASED FATIGUE AND  
DEVELOPMENT OF DIARRHEA  
WITH BLACK STOOL. WE  
RECOMMENDED GOING TO  
EDC (WHICH HAD ALSO BEEN  
RECOMMENDED BY PCP). HE  
WAS ADMITTED FROM THE ED  
AND DIAGNOSED AS ABOVE.

PATIENT DOES HAVE  
UNDERLYING CONDITIONS  
SUCH AS DIABETES, HIGH  
CHOLESTEROL,  
HYPERTENSION, AND CABG.

|                                                            |   |
|------------------------------------------------------------|---|
| 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 |

US3762161

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:14:36

|                                                                |                                                                                                                                                                  |
|----------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| AEID                                                           | USA-US130-2020-MRNA-1273-P30<br>1000001                                                                                                                          |
| Adverse event                                                  | ACUTE KIDNEY INJURY                                                                                                                                              |
| 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)                                       | 10 NOV 2020                                                                                                                                                      |
| Start time (00:00-23:59)                                       |                                                                                                                                                                  |
| AE start date and time (derived)                               |                                                                                                                                                                  |
| Ongoing?                                                       | Yes <input type="radio"/><br>No <input checked="" type="radio"/>                                                                                                 |
| If not Ongoing, end date (dd MMM yyyy)                         | 11 NOV 2020                                                                                                                                                      |
| End time (00:00-23:59)                                         |                                                                                                                                                                  |
| AE End Date and Time (derived)                                 |                                                                                                                                                                  |
| Severity                                                       | Grade 1/Mild <input type="radio"/><br>Grade 2/Moderate <input type="radio"/><br>Grade 3/Severe <input checked="" type="radio"/><br>Grade 4 <input type="radio"/> |
| Is the adverse event serious?                                  | Yes <input checked="" type="radio"/><br>No <input type="radio"/>                                                                                                 |
| AE is serious due To (check all that apply)                    |                                                                                                                                                                  |
| Death                                                          | False                                                                                                                                                            |
| Life threatening                                               | True                                                                                                                                                             |
| Requires inpatient or prolongation of existing Hospitalization | True                                                                                                                                                             |
| Hospital Admission Date (dd MMM yyyy)                          | 10 NOV 2020                                                                                                                                                      |
| Hospital Discharge Date (dd MMM yyyy)                          | 15 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)                                              | 371 of 2361                                                                                                                                                      |

US3762161

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:14:36

|                                                                              |                                                                                                                                                                                                                                                                                 |
|------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 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                                                        | False                                                                                                                                                                                                                                                                           |
| Outcome                                                                      | Fatal <input type="radio"/><br>Not Recovered/Not Resolved <input type="radio"/><br>Recovered/Resolved <input checked="" type="radio"/><br>Recovered/Resolved with Sequelae <input type="radio"/><br>Recovering/Resolving <input type="radio"/><br>Unknown <input type="radio"/> |
| If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: |                                                                                                                                                                                                                                                                                 |
| Narrative                                                                    |                                                                                                                                                                                                                                                                                 |

US3762161

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:14:36

74 Y/O MALE WHO RECEIVED  
SECOND DOSE OF PRODUCT ON  
9/30 WITHOUT INCIDENT AND  
WAS SEEN FOR ROUTINE F/U  
ON 11/03 AND REPORTED NO  
SYMPTOMS WHO WAS  
ADMITTED TO WFBMC ON 11/10  
WITH DIAGNOSIS OF  
GASTROENTERITIS WITH  
ASSOCIATED SEPSIS, ACUTE  
KIDNEY INJURY, AND  
POSSIBLE GI BLEED. HE HAD  
REPORTED FEELING TIRED  
WITH HEADACHES AND  
MUSCLE ACHES ON 11/09 AND  
WAS SEEN FOR A SICK VISIT. A  
PCR FOR COVID-19 WAS  
PERFORMED AT THE TIME WAS  
NEGATIVE. ON TELEPHONE F/U  
ON 11/10, HE REPORTED  
INCREASED FATIGUE AND  
DEVELOPMENT OF DIARRHEA  
WITH BLACK STOOL. WE  
RECOMMENDED GOING TO  
EDC (WHICH HAD ALSO BEEN  
RECOMMENDED BY PCP). HE  
WAS ADMITTED FROM THE ED  
AND DIAGNOSED AS ABOVE.

CREATININE:  
11/10/20 17:59= 1.75  
11/11/20 06:41= 1.32  
11/12/07:02= 1.41  
11/13/20 06:15= 1.53  
11/14/20 08:01= 1.41

|                                                            |   |
|------------------------------------------------------------|---|
| 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 |

US3762161

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:14:36

|                                                                |                                                                                                                                                                  |
|----------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| AEID                                                           | USA-US130-2020-MRNA-1273-P30<br>1000001                                                                                                                          |
| Adverse event                                                  | DIARRHEA                                                                                                                                                         |
| 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)                                       | 9 NOV 2020                                                                                                                                                       |
| Start time (00:00-23:59)                                       |                                                                                                                                                                  |
| AE start date and time (derived)                               |                                                                                                                                                                  |
| Ongoing?                                                       | Yes <input type="radio"/><br>No <input checked="" type="radio"/>                                                                                                 |
| If not Ongoing, end date (dd MMM yyyy)                         | 15 NOV 2020                                                                                                                                                      |
| End time (00:00-23:59)                                         |                                                                                                                                                                  |
| AE End Date and Time (derived)                                 |                                                                                                                                                                  |
| Severity                                                       | Grade 1/Mild <input type="radio"/><br>Grade 2/Moderate <input type="radio"/><br>Grade 3/Severe <input checked="" type="radio"/><br>Grade 4 <input type="radio"/> |
| Is the adverse event serious?                                  | Yes <input checked="" type="radio"/><br>No <input type="radio"/>                                                                                                 |
| AE is serious due To (check all that apply)                    |                                                                                                                                                                  |
| Death                                                          | False                                                                                                                                                            |
| Life threatening                                               | True                                                                                                                                                             |
| Requires inpatient or prolongation of existing Hospitalization | True                                                                                                                                                             |
| Hospital Admission Date (dd MMM yyyy)                          | 10 NOV 2020                                                                                                                                                      |
| Hospital Discharge Date (dd MMM yyyy)                          | 15 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)                                              | 374 of 2361                                                                                                                                                      |

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:14:36

|                                                                              |                                                                                                                                                                                                                                                                                 |
|------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 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                                                        | False                                                                                                                                                                                                                                                                           |
| Outcome                                                                      | Fatal <input type="radio"/><br>Not Recovered/Not Resolved <input type="radio"/><br>Recovered/Resolved <input checked="" type="radio"/><br>Recovered/Resolved with Sequelae <input type="radio"/><br>Recovering/Resolving <input type="radio"/><br>Unknown <input type="radio"/> |
| If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: |                                                                                                                                                                                                                                                                                 |
| Narrative                                                                    |                                                                                                                                                                                                                                                                                 |



US3762161

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:14:36

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74 Y/O MALE WHO RECEIVED  
SECOND DOSE OF PRODUCT ON  
9/30 WITHOUT INCIDENT AND  
WAS SEEN FOR ROUTINE F/U  
ON 11/03 AND REPORTED NO  
SYMPTOMS WHO WAS  
ADMITTED TO WFBMC ON 11/10  
WITH DIAGNOSIS OF  
GASTROENTERITIS WITH  
ASSOCIATED SEPSIS, ACUTE  
KIDNEY INJURY, AND  
POSSIBLE GI BLEED. HE HAD  
REPORTED FEELING TIRED  
WITH HEADACHES AND  
MUSCLE ACHES ON 11/09 AND  
WAS SEEN FOR A SICK VISIT. A  
PCR FOR COVID-19 WAS  
PERFORMED AT THE TIME WAS  
NEGATIVE. ON TELEPHONE F/U  
ON 11/10, HE REPORTED  
INCREASED FATIGUE AND  
DEVELOPMENT OF DIARRHEA  
WITH BLACK STOOL. WE  
RECOMMENDED GOING TO  
EDC (WHICH HAD ALSO BEEN  
RECOMMENDED BY PCP). HE  
WAS ADMITTED FROM THE ED  
AND DIAGNOSED AS ABOVE.

---

|                                                            |   |
|------------------------------------------------------------|---|
| 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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US3762161

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:14:36

|                                                                |                                                                                                                                                                  |
|----------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| AEID                                                           | USA-US130-2020-MRNA-1273-P30<br>1000001                                                                                                                          |
| Adverse event                                                  | LEFT UPPER LOBE PNEUMONIA                                                                                                                                        |
| 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)                                       | 10 NOV 2020                                                                                                                                                      |
| Start time (00:00-23:59)                                       |                                                                                                                                                                  |
| AE start date and time (derived)                               |                                                                                                                                                                  |
| Ongoing?                                                       | Yes <input type="radio"/><br>No <input checked="" type="radio"/>                                                                                                 |
| If not Ongoing, end date (dd MMM yyyy)                         | 18 NOV 2020                                                                                                                                                      |
| End time (00:00-23:59)                                         |                                                                                                                                                                  |
| AE End Date and Time (derived)                                 |                                                                                                                                                                  |
| Severity                                                       | Grade 1/Mild <input type="radio"/><br>Grade 2/Moderate <input type="radio"/><br>Grade 3/Severe <input checked="" type="radio"/><br>Grade 4 <input type="radio"/> |
| Is the adverse event serious?                                  | Yes <input checked="" type="radio"/><br>No <input type="radio"/>                                                                                                 |
| AE is serious due To (check all that apply)                    |                                                                                                                                                                  |
| Death                                                          | False                                                                                                                                                            |
| Life threatening                                               | False                                                                                                                                                            |
| Requires inpatient or prolongation of existing Hospitalization | True                                                                                                                                                             |
| Hospital Admission Date (dd MMM yyyy)                          | 10 NOV 2020                                                                                                                                                      |
| Hospital Discharge Date (dd MMM yyyy)                          | 15 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)                                              | 377 of 2361                                                                                                                                                      |

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:14:36

|                                                                              |                                                                                                                                                                                                                                                                                 |
|------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 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                                                        | False                                                                                                                                                                                                                                                                           |
| Outcome                                                                      | Fatal <input type="radio"/><br>Not Recovered/Not Resolved <input type="radio"/><br>Recovered/Resolved <input checked="" type="radio"/><br>Recovered/Resolved with Sequelae <input type="radio"/><br>Recovering/Resolving <input type="radio"/><br>Unknown <input type="radio"/> |
| If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: |                                                                                                                                                                                                                                                                                 |
| Narrative                                                                    |                                                                                                                                                                                                                                                                                 |

US3762161

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:14:36

74 Y/O MALE WHO RECEIVED  
SECOND DOSE OF PRODUCT ON  
9/30 WITHOUT INCIDENT AND  
WAS SEEN FOR ROUTINE F/U  
ON 11/03 AND REPORTED NO  
SYMPTOMS WHO WAS  
ADMITTED TO WFBMC ON 11/10  
WITH DIAGNOSIS OF  
GASTROENTERITIS WITH  
ASSOCIATED SEPSIS, ACUTE  
KIDNEY INJURY, AND  
POSSIBLE GI BLEED. HE HAD  
REPORTED FEELING TIRED  
WITH HEADACHES AND  
MUSCLE ACHES ON 11/09 AND  
WAS SEEN FOR A SICK VISIT. A  
PCR FOR COVID-19 WAS  
PERFORMED AT THE TIME WAS  
NEGATIVE. ON TELEPHONE F/U  
ON 11/10, HE REPORTED  
INCREASED FATIGUE AND  
DEVELOPMENT OF DIARRHEA  
WITH BLACK STOOL. WE  
RECOMMENDED GOING TO  
EDC (WHICH HAD ALSO BEEN  
RECOMMENDED BY PCP). HE  
WAS ADMITTED FROM THE ED  
AND DIAGNOSED AS ABOVE.

CT CHEST SCAN WITHOUT  
CONTRAST WAS PERFORMED

|                                                            |   |
|------------------------------------------------------------|---|
| 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 |

US3762161

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:14:36

|                                                                |                                                                                                                                                                  |
|----------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| AEID                                                           | USA-US130-2020-MRNA-1273-P30<br>1000001                                                                                                                          |
| Adverse event                                                  | ACUTE HYPONATREMIA                                                                                                                                               |
| 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)                                       | 10 NOV 2020                                                                                                                                                      |
| Start time (00:00-23:59)                                       |                                                                                                                                                                  |
| AE start date and time (derived)                               |                                                                                                                                                                  |
| Ongoing?                                                       | Yes <input type="radio"/><br>No <input checked="" type="radio"/>                                                                                                 |
| If not Ongoing, end date (dd MMM yyyy)                         | 15 NOV 2020                                                                                                                                                      |
| End time (00:00-23:59)                                         |                                                                                                                                                                  |
| AE End Date and Time (derived)                                 |                                                                                                                                                                  |
| Severity                                                       | Grade 1/Mild <input checked="" type="radio"/><br>Grade 2/Moderate <input type="radio"/><br>Grade 3/Severe <input type="radio"/><br>Grade 4 <input type="radio"/> |
| Is the adverse event serious?                                  | Yes <input 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)                          | 10 NOV 2020                                                                                                                                                      |
| Hospital Discharge Date (dd MMM yyyy)                          | 15 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)                                              | 380 of 2361                                                                                                                                                      |

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:14:36

|                                                                              |                                                                                                                                                                                                                                                                                 |
|------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 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                                                                         | True                                                                                                                                                                                                                                                                            |
| Concomitant Medication                                                       | False                                                                                                                                                                                                                                                                           |
| Concomitant Procedure                                                        | False                                                                                                                                                                                                                                                                           |
| Outcome                                                                      | Fatal <input type="radio"/><br>Not Recovered/Not Resolved <input type="radio"/><br>Recovered/Resolved <input checked="" type="radio"/><br>Recovered/Resolved with Sequelae <input type="radio"/><br>Recovering/Resolving <input type="radio"/><br>Unknown <input type="radio"/> |
| If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: |                                                                                                                                                                                                                                                                                 |
| Narrative                                                                    |                                                                                                                                                                                                                                                                                 |

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:14:36

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74 Y/O MALE WHO RECEIVED  
SECOND DOSE OF PRODUCT ON  
9/30 WITHOUT INCIDENT AND  
WAS SEEN FOR ROUTINE F/U  
ON 11/03 AND REPORTED NO  
SYMPTOMS WHO WAS  
ADMITTED TO WFBMC ON 11/10  
WITH DIAGNOSIS OF  
GASTROENTERITIS WITH  
ASSOCIATED SEPSIS, ACUTE  
KIDNEY INJURY, AND  
POSSIBLE GI BLEED. HE HAD  
REPORTED FEELING TIRED  
WITH HEADACHES AND  
MUSCLE ACHES ON 11/09 AND  
WAS SEEN FOR A SICK VISIT. A  
PCR FOR COVID-19 WAS  
PERFORMED AT THE TIME WAS  
NEGATIVE. ON TELEPHONE F/U  
ON 11/10, HE REPORTED  
INCREASED FATIGUE AND  
DEVELOPMENT OF DIARRHEA  
WITH BLACK STOOL. WE  
RECOMMENDED GOING TO  
EDC (WHICH HAD ALSO BEEN  
RECOMMENDED BY PCP). HE  
WAS ADMITTED FROM THE ED  
AND DIAGNOSED AS ABOVE.

---

|                                                            |   |
|------------------------------------------------------------|---|
| 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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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:14:36

|                                                                |                                                                                                                                                                  |
|----------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| AEID                                                           | USA-US130-2020-MRNA-1273-P30<br>1000001                                                                                                                          |
| Adverse event                                                  | HYPOKALEMIA                                                                                                                                                      |
| 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)                                       | 10 NOV 2020                                                                                                                                                      |
| Start time (00:00-23:59)                                       |                                                                                                                                                                  |
| AE start date and time (derived)                               |                                                                                                                                                                  |
| Ongoing?                                                       | Yes <input type="radio"/><br>No <input checked="" type="radio"/>                                                                                                 |
| If not Ongoing, end date (dd MMM yyyy)                         | 15 NOV 2020                                                                                                                                                      |
| End time (00:00-23:59)                                         |                                                                                                                                                                  |
| AE End Date and Time (derived)                                 |                                                                                                                                                                  |
| Severity                                                       | Grade 1/Mild <input checked="" type="radio"/><br>Grade 2/Moderate <input type="radio"/><br>Grade 3/Severe <input type="radio"/><br>Grade 4 <input type="radio"/> |
| Is the adverse event serious?                                  | Yes <input 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)                          | 10 NOV 2020                                                                                                                                                      |
| Hospital Discharge Date (dd MMM yyyy)                          | 15 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)                                              | 383 of 2361                                                                                                                                                      |



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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:14:36

|                                                                              |                                                                                                                                                                                                                                                                                 |
|------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 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                                                                         | True                                                                                                                                                                                                                                                                            |
| Concomitant Medication                                                       | False                                                                                                                                                                                                                                                                           |
| Concomitant Procedure                                                        | False                                                                                                                                                                                                                                                                           |
| Outcome                                                                      | Fatal <input type="radio"/><br>Not Recovered/Not Resolved <input type="radio"/><br>Recovered/Resolved <input checked="" type="radio"/><br>Recovered/Resolved with Sequelae <input type="radio"/><br>Recovering/Resolving <input type="radio"/><br>Unknown <input type="radio"/> |
| If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: |                                                                                                                                                                                                                                                                                 |
| Narrative                                                                    |                                                                                                                                                                                                                                                                                 |

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:14:36

74 Y/O MALE WHO RECEIVED  
SECOND DOSE OF PRODUCT ON  
9/30 WITHOUT INCIDENT AND  
WAS SEEN FOR ROUTINE F/U  
ON 11/03 AND REPORTED NO  
SYMPTOMS WHO WAS  
ADMITTED TO WFBMC ON 11/10  
WITH DIAGNOSIS OF  
GASTROENTERITIS WITH  
ASSOCIATED SEPSIS, ACUTE  
KIDNEY INJURY, AND  
POSSIBLE GI BLEED. HE HAD  
REPORTED FEELING TIRED  
WITH HEADACHES AND  
MUSCLE ACHES ON 11/09 AND  
WAS SEEN FOR A SICK VISIT. A  
PCR FOR COVID-19 WAS  
PERFORMED AT THE TIME WAS  
NEGATIVE. ON TELEPHONE F/U  
ON 11/10, HE REPORTED  
INCREASED FATIGUE AND  
DEVELOPMENT OF DIARRHEA  
WITH BLACK STOOL. WE  
RECOMMENDED GOING TO  
EDC (WHICH HAD ALSO BEEN  
RECOMMENDED BY PCP). HE  
WAS ADMITTED FROM THE ED  
AND DIAGNOSED AS ABOVE.

|                                                            |   |
|------------------------------------------------------------|---|
| 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 |

US3762161

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:14:36

|                                                                |                                                                                                                                                                  |
|----------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| AEID                                                           | USA-US130-2020-MRNA-1273-P30<br>1000001                                                                                                                          |
| Adverse event                                                  | [DIARRHEA WITH]<br>DEHYDRATION                                                                                                                                   |
| 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)                                       | 09 NOV 2020                                                                                                                                                      |
| Start time (00:00-23:59)                                       |                                                                                                                                                                  |
| AE start date and time (derived)                               |                                                                                                                                                                  |
| Ongoing?                                                       | Yes <input type="radio"/><br>No <input checked="" type="radio"/>                                                                                                 |
| If not Ongoing, end date (dd MMM yyyy)                         | 15 NOV 2020                                                                                                                                                      |
| End time (00:00-23:59)                                         |                                                                                                                                                                  |
| AE End Date and Time (derived)                                 |                                                                                                                                                                  |
| Severity                                                       | Grade 1/Mild <input type="radio"/><br>Grade 2/Moderate <input checked="" type="radio"/><br>Grade 3/Severe <input type="radio"/><br>Grade 4 <input type="radio"/> |
| Is the adverse event serious?                                  | Yes <input 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)                          | 10 NOV 2020                                                                                                                                                      |
| Hospital Discharge Date (dd MMM yyyy)                          | 15 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                                          |                                                                                                                                                                  |

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:14:36

|                                                                              |                                                                                                                                                                                                                                                                                 |
|------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 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                                                                         | True                                                                                                                                                                                                                                                                            |
| Concomitant Medication                                                       | False                                                                                                                                                                                                                                                                           |
| Concomitant Procedure                                                        | False                                                                                                                                                                                                                                                                           |
| Outcome                                                                      | Fatal <input type="radio"/><br>Not Recovered/Not Resolved <input type="radio"/><br>Recovered/Resolved <input checked="" type="radio"/><br>Recovered/Resolved with Sequelae <input type="radio"/><br>Recovering/Resolving <input type="radio"/><br>Unknown <input type="radio"/> |
| If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: |                                                                                                                                                                                                                                                                                 |
| Narrative                                                                    |                                                                                                                                                                                                                                                                                 |

US3762161

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:14:36

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74 Y/O MALE WHO RECEIVED  
SECOND DOSE OF PRODUCT ON  
9/30 WITHOUT INCIDENT AND  
WAS SEEN FOR ROUTINE F/U  
ON 11/03 AND REPORTED NO  
SYMPTOMS WHO WAS  
ADMITTED TO WFBMC ON 11/10  
WITH DIAGNOSIS OF  
GASTROENTERITIS WITH  
ASSOCIATED SEPSIS, ACUTE  
KIDNEY INJURY, AND  
POSSIBLE GI BLEED. HE HAD  
REPORTED FEELING TIRED  
WITH HEADACHES AND  
MUSCLE ACHES ON 11/09 AND  
WAS SEEN FOR A SICK VISIT. A  
PCR FOR COVID-19 WAS  
PERFORMED AT THE TIME WAS  
NEGATIVE. ON TELEPHONE F/U  
ON 11/10, HE REPORTED  
INCREASED FATIGUE AND  
DEVELOPMENT OF DIARRHEA  
WITH BLACK STOOL. WE  
RECOMMENDED GOING TO  
EDC (WHICH HAD ALSO BEEN  
RECOMMENDED BY PCP). HE  
WAS ADMITTED FROM THE ED  
AND DIAGNOSED AS ABOVE.

---

|                                                            |   |
|------------------------------------------------------------|---|
| 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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US3762161

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 11:14:36

|                                                                |                                                                                                                                                                  |
|----------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| AEID                                                           |                                                                                                                                                                  |
| Adverse event                                                  | GASTROENTERITIS                                                                                                                                                  |
| 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)                                       | 10 NOV 2020                                                                                                                                                      |
| Start time (00:00-23:59)                                       |                                                                                                                                                                  |
| AE start date and time (derived)                               |                                                                                                                                                                  |
| Ongoing?                                                       | Yes <input type="radio"/><br>No <input checked="" type="radio"/>                                                                                                 |
| If not Ongoing, end date (dd MMM yyyy)                         | 15 NOV 2020                                                                                                                                                      |
| End time (00:00-23:59)                                         |                                                                                                                                                                  |
| AE End Date and Time (derived)                                 |                                                                                                                                                                  |
| Severity                                                       | Grade 1/Mild <input type="radio"/><br>Grade 2/Moderate <input checked="" type="radio"/><br>Grade 3/Severe <input type="radio"/><br>Grade 4 <input type="radio"/> |
| Is the adverse event serious?                                  | Yes <input 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)                          | 10 NOV 2020                                                                                                                                                      |
| Hospital Discharge Date (dd MMM yyyy)                          | 15 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                                          |                                                                                                                                                                  |
| Persistent or significant disability or incapacity             | False                                                                                                                                                            |
| v6.020 DTW (1102)                                              | 389 of 2361                                                                                                                                                      |

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 11:14:36

|                                                                              |                                                                                                                                                                                                                                                                                 |
|------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Congenital anomaly or birth defect                                           | False                                                                                                                                                                                                                                                                           |
| Other medically important event                                              | False                                                                                                                                                                                                                                                                           |
| Relationship to investigational product                                      | Not Related <input checked="" type="radio"/><br>Related <input type="radio"/><br>Not Applicable <input type="radio"/>                                                                                                                                                           |
| Relationship to Study Procedure                                              | Not Related <input checked="" type="radio"/><br>Related <input type="radio"/><br>Not Applicable <input type="radio"/>                                                                                                                                                           |
| Action taken with investigational product                                    | None <input type="radio"/><br>Dose Delayed <input type="radio"/><br>Investigational Product Withdrawn <input type="radio"/><br>Not Applicable <input checked="" type="radio"/>                                                                                                  |
| Other action taken (check all that apply)                                    |                                                                                                                                                                                                                                                                                 |
| None                                                                         | True                                                                                                                                                                                                                                                                            |
| Concomitant Medication                                                       | False                                                                                                                                                                                                                                                                           |
| Concomitant Procedure                                                        | False                                                                                                                                                                                                                                                                           |
| Outcome                                                                      | Fatal <input type="radio"/><br>Not Recovered/Not Resolved <input type="radio"/><br>Recovered/Resolved <input checked="" type="radio"/><br>Recovered/Resolved with Sequelae <input type="radio"/><br>Recovering/Resolving <input type="radio"/><br>Unknown <input type="radio"/> |
| If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: |                                                                                                                                                                                                                                                                                 |
| Narrative                                                                    |                                                                                                                                                                                                                                                                                 |

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 11:14:36

74 Y/O MALE WHO RECEIVED  
SECOND DOSE OF PRODUCT ON  
9/30 WITHOUT INCIDENT AND  
WAS SEEN FOR ROUTINE F/U  
ON 11/03 AND REPORTED NO  
SYMPTOMS WHO WAS  
ADMITTED TO WFBMC ON 11/10  
WITH DIAGNOSIS OF  
GASTROENTERITIS WITH  
ASSOCIATED SEPSIS, ACUTE  
KIDNEY INJURY, AND  
POSSIBLE GI BLEED. HE HAD  
REPORTED FEELING TIRED  
WITH HEADACHES AND  
MUSCLE ACHES ON 11/09 AND  
WAS SEEN FOR A SICK VISIT. A  
PCR FOR COVID-19 WAS  
PERFORMED AT THE TIME WAS  
NEGATIVE. ON TELEPHONE F/U  
ON 11/10, HE REPORTED  
INCREASED FATIGUE AND  
DEVELOPMENT OF DIARRHEA  
WITH BLACK STOOL. WE  
RECOMMENDED GOING TO  
EDC (WHICH HAD ALSO BEEN  
RECOMMENDED BY PCP). HE  
WAS ADMITTED FROM THE ED  
AND DIAGNOSED AS ABOVE.

CT ABDOMEN/PELVIS WITH  
CONTRAST

|                                                            |   |
|------------------------------------------------------------|---|
| 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 |



US3762161

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

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

**Generated On: 26 Nov 2020 11:14:36**

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

Yes ☒

No ☐

---

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

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US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:14:36

|                                      |                                                                                                                                                                                                                                                                                                                                                                                                                          |
|--------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Name of Medication                   | LISINOPRIL                                                                                                                                                                                                                                                                                                                                                                                                               |
| Prophylaxis                          | Yes <input checked="" type="radio"/><br>No <input type="radio"/>                                                                                                                                                                                                                                                                                                                                                         |
| Indication                           | HIGH CHOLESTEROL                                                                                                                                                                                                                                                                                                                                                                                                         |
| Dose per administration              | 10                                                                                                                                                                                                                                                                                                                                                                                                                       |
| Dose unit                            | mg <input checked="" type="radio"/><br>ug <input type="radio"/><br>mL <input type="radio"/><br>g <input type="radio"/><br>IU <input type="radio"/><br>tablet <input type="radio"/><br>capsule <input type="radio"/><br>puff <input type="radio"/><br>Other <input type="radio"/>                                                                                                                                         |
| If dose unit is Other, specify _____ |                                                                                                                                                                                                                                                                                                                                                                                                                          |
| Frequency                            | once daily <input checked="" type="radio"/><br>twice daily <input type="radio"/><br>three times daily <input type="radio"/><br>four times daily <input type="radio"/><br>every other day <input type="radio"/><br>every week <input type="radio"/><br>every month <input type="radio"/><br>as needed <input type="radio"/><br>once <input type="radio"/><br>unknown <input type="radio"/><br>other <input type="radio"/> |
| If frequency is Other, specify _____ |                                                                                                                                                                                                                                                                                                                                                                                                                          |
| Route of administration              | Oral <input checked="" type="radio"/><br>Topical <input type="radio"/><br>Subcutaneous <input type="radio"/><br>Transdermal <input type="radio"/><br>Intraocular <input type="radio"/><br>Intramuscular <input type="radio"/>                                                                                                                                                                                            |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:14:36

|                                                    |                                      |
|----------------------------------------------------|--------------------------------------|
| 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"/>             |
| If route of administration is Other, specify _____ |                                      |
| Start date (dd MMM yyyy)                           | UN AUG 2000                          |
| Start date completely unknown                      | False                                |
| Ongoing?                                           | Yes <input checked="" type="radio"/> |
|                                                    | No <input type="radio"/>             |
| If not Ongoing, End date (dd MMM yyyy) _____       |                                      |
| Was this medication taken for solicited event?     | Yes <input type="radio"/>            |
|                                                    | No <input checked="" type="radio"/>  |
| Separate Dosage Number (derived)                   | 1                                    |
| Interval Dosage Unit Number (derived)              | 1                                    |
| Interval Dosage Definition (derived)               | 802 <input type="radio"/>            |
|                                                    | 803 <input type="radio"/>            |
|                                                    | 804 <input checked="" type="radio"/> |

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:14:36

|                                |                                                                                                                                                                                                                                                                                                                                                                                                                          |
|--------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Name of Medication             | ATORVASTATIN                                                                                                                                                                                                                                                                                                                                                                                                             |
| Prophylaxis                    | Yes <input type="radio"/><br>No <input checked="" type="radio"/>                                                                                                                                                                                                                                                                                                                                                         |
| Indication                     | HIGH CHOLESTEROL                                                                                                                                                                                                                                                                                                                                                                                                         |
| Dose per administration        | 80                                                                                                                                                                                                                                                                                                                                                                                                                       |
| 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 (2)

Generated On: 26 Nov 2020 11:14:36

|                                                    |                                      |
|----------------------------------------------------|--------------------------------------|
| 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"/>             |
| If route of administration is Other, specify _____ |                                      |
| Start date (dd MMM yyyy)                           | UN FEB 2007                          |
| Start date completely unknown                      | False                                |
| Ongoing?                                           | Yes <input checked="" type="radio"/> |
|                                                    | No <input type="radio"/>             |
| If not Ongoing, End date (dd MMM yyyy) _____       |                                      |
| Was this medication taken for solicited event?     | Yes <input type="radio"/>            |
|                                                    | No <input checked="" type="radio"/>  |
| Separate Dosage Number (derived)                   | 1                                    |
| Interval Dosage Unit Number (derived)              | 1                                    |
| Interval Dosage Definition (derived)               | 802 <input type="radio"/>            |
|                                                    | 803 <input type="radio"/>            |
|                                                    | 804 <input checked="" type="radio"/> |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:14:36

|                                      |                                                                                                                                                                                                                                                                                                                                                                                                                          |
|--------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Name of Medication                   | METFORMIN                                                                                                                                                                                                                                                                                                                                                                                                                |
| Prophylaxis                          | Yes <input type="radio"/><br>No <input checked="" type="radio"/>                                                                                                                                                                                                                                                                                                                                                         |
| Indication                           | TYPE II DIABETES                                                                                                                                                                                                                                                                                                                                                                                                         |
| 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 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 (3)

Generated On: 26 Nov 2020 11:14:36

|                                                                   |                          |                                  |
|-------------------------------------------------------------------|--------------------------|----------------------------------|
|                                                                   | Respiratory (Inhalation) | <input type="checkbox"/>         |
|                                                                   | Intralesional            | <input type="checkbox"/>         |
|                                                                   | Intraperitoneal          | <input type="checkbox"/>         |
|                                                                   | Nasal                    | <input type="checkbox"/>         |
|                                                                   | Vaginal                  | <input type="checkbox"/>         |
|                                                                   | Rectal                   | <input type="checkbox"/>         |
|                                                                   | Intravenous              | <input type="checkbox"/>         |
|                                                                   | Intravenous Bolus        | <input type="checkbox"/>         |
|                                                                   | Intravenous Drip         | <input type="checkbox"/>         |
|                                                                   | Other                    | <input type="checkbox"/>         |
| <hr/>                                                             |                          |                                  |
| If route of administration is Other, specify <input type="text"/> |                          |                                  |
| <hr/>                                                             |                          |                                  |
| Start date (dd MMM yyyy)                                          | UN FEB 2007              |                                  |
| Start date completely unknown                                     | False                    |                                  |
| Ongoing?                                                          | Yes                      | <input checked="" type="radio"/> |
|                                                                   | No                       | <input type="radio"/>            |
| <hr/>                                                             |                          |                                  |
| If not Ongoing, End date (dd MMM yyyy) <input type="text"/>       |                          |                                  |
| <hr/>                                                             |                          |                                  |
| Was this medication taken for solicited event?                    | Yes                      | <input type="radio"/>            |
|                                                                   | No                       | <input checked="" type="radio"/> |
| <hr/>                                                             |                          |                                  |
| Separate Dosage Number (derived)                                  | 1                        |                                  |
| Interval Dosage Unit Number (derived)                             | 1                        |                                  |
| Interval Dosage Definition (derived)                              | 802                      | <input type="radio"/>            |
|                                                                   | 803                      | <input type="radio"/>            |
|                                                                   | 804                      | <input checked="" type="radio"/> |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:14:36

|                                      |                                                                                                                                                                                                                                                                                                                                                                                                                          |
|--------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Name of Medication                   | GABAPENTIN                                                                                                                                                                                                                                                                                                                                                                                                               |
| Prophylaxis                          | Yes <input checked="" type="radio"/><br>No <input type="radio"/>                                                                                                                                                                                                                                                                                                                                                         |
| Indication                           | NEUROPATHY                                                                                                                                                                                                                                                                                                                                                                                                               |
| Dose per administration              | 800                                                                                                                                                                                                                                                                                                                                                                                                                      |
| 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 checked="" 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)

Generated On: 26 Nov 2020 11:14:36

|                                                    |                          |                                  |
|----------------------------------------------------|--------------------------|----------------------------------|
|                                                    | 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)                           | UN UNK 2010              |                                  |
| 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)                   | 4                        |                                  |
| 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)

Generated On: 26 Nov 2020 11:14:36

|                                      |                                                                                                                                                                                                                                                                                                                                                                                                                          |
|--------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Name of Medication                   | ASPIRIN                                                                                                                                                                                                                                                                                                                                                                                                                  |
| Prophylaxis                          | Yes <input checked="" type="radio"/><br>No <input type="radio"/>                                                                                                                                                                                                                                                                                                                                                         |
| Indication                           | HEART HEALTH                                                                                                                                                                                                                                                                                                                                                                                                             |
| Dose per administration              | 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 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"/>                                                                                                                                                                                            |

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:14:36

|                                                                   |                          |                                  |
|-------------------------------------------------------------------|--------------------------|----------------------------------|
|                                                                   | Respiratory (Inhalation) | <input type="checkbox"/>         |
|                                                                   | Intralesional            | <input type="checkbox"/>         |
|                                                                   | Intraperitoneal          | <input type="checkbox"/>         |
|                                                                   | Nasal                    | <input type="checkbox"/>         |
|                                                                   | Vaginal                  | <input type="checkbox"/>         |
|                                                                   | Rectal                   | <input type="checkbox"/>         |
|                                                                   | Intravenous              | <input type="checkbox"/>         |
|                                                                   | Intravenous Bolus        | <input type="checkbox"/>         |
|                                                                   | Intravenous Drip         | <input type="checkbox"/>         |
|                                                                   | Other                    | <input type="checkbox"/>         |
| <hr/>                                                             |                          |                                  |
| If route of administration is Other, specify <input type="text"/> |                          |                                  |
| <hr/>                                                             |                          |                                  |
| Start date (dd MMM yyyy)                                          | UN                       | UNK 2005                         |
| Start date completely unknown                                     | False                    |                                  |
| Ongoing?                                                          | Yes                      | <input checked="" type="radio"/> |
|                                                                   | No                       | <input type="radio"/>            |
| <hr/>                                                             |                          |                                  |
| If not Ongoing, End date (dd MMM yyyy) <input type="text"/>       |                          |                                  |
| <hr/>                                                             |                          |                                  |
| Was this medication taken for solicited event?                    | Yes                      | <input type="radio"/>            |
|                                                                   | No                       | <input checked="" type="radio"/> |
| <hr/>                                                             |                          |                                  |
| Separate Dosage Number (derived)                                  | 1                        |                                  |
| Interval Dosage Unit Number (derived)                             | 1                        |                                  |
| Interval Dosage Definition (derived)                              | 802                      | <input type="radio"/>            |
|                                                                   | 803                      | <input type="radio"/>            |
|                                                                   | 804                      | <input checked="" type="radio"/> |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:14:36

|                                      |                                                                                                                                                                                                                                                                                                                                                                                                                          |
|--------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Name of Medication                   | HUMALOG                                                                                                                                                                                                                                                                                                                                                                                                                  |
| Prophylaxis                          | Yes <input checked="" type="radio"/><br>No <input type="radio"/>                                                                                                                                                                                                                                                                                                                                                         |
| Indication                           | TYPE II DIABETES                                                                                                                                                                                                                                                                                                                                                                                                         |
| Dose per administration              | 100                                                                                                                                                                                                                                                                                                                                                                                                                      |
| 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 type="radio"/><br>twice daily <input type="radio"/><br>three times daily <input type="radio"/><br>four times daily <input checked="" 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 type="radio"/><br>Topical <input type="radio"/><br>Subcutaneous <input checked="" type="radio"/><br>Transdermal <input type="radio"/><br>Intraocular <input type="radio"/><br>Intramuscular <input type="radio"/>                                                                                                                                                                                            |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:14:36

|                                                                   |                          |                                  |
|-------------------------------------------------------------------|--------------------------|----------------------------------|
|                                                                   | Respiratory (Inhalation) | <input type="checkbox"/>         |
|                                                                   | Intralesional            | <input type="checkbox"/>         |
|                                                                   | Intraperitoneal          | <input type="checkbox"/>         |
|                                                                   | Nasal                    | <input type="checkbox"/>         |
|                                                                   | Vaginal                  | <input type="checkbox"/>         |
|                                                                   | Rectal                   | <input type="checkbox"/>         |
|                                                                   | Intravenous              | <input type="checkbox"/>         |
|                                                                   | Intravenous Bolus        | <input type="checkbox"/>         |
|                                                                   | Intravenous Drip         | <input type="checkbox"/>         |
|                                                                   | Other                    | <input type="checkbox"/>         |
| <hr/>                                                             |                          |                                  |
| If route of administration is Other, specify <input type="text"/> |                          |                                  |
| <hr/>                                                             |                          |                                  |
| Start date (dd MMM yyyy)                                          | UN                       | UNK 1998                         |
| 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)                                  | 4                        |                                  |
| 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             | LEVEMIR                                                                                                                                                                                                                                                                                                                                                                                                                  |
| Prophylaxis                    | Yes <input type="radio"/><br>No <input checked="" type="radio"/>                                                                                                                                                                                                                                                                                                                                                         |
| Indication                     | TYPE II DIABETES                                                                                                                                                                                                                                                                                                                                                                                                         |
| Dose per administration        | 56                                                                                                                                                                                                                                                                                                                                                                                                                       |
| 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 type="radio"/><br>Topical <input type="radio"/><br>Subcutaneous <input checked="" 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)                                          | UN                       | UNK 2007                         |
| Start date completely unknown                                     | False                    |                                  |
| Ongoing?                                                          | Yes                      | <input checked="" type="radio"/> |
|                                                                   | No                       | <input type="radio"/>            |
| <hr/>                                                             |                          |                                  |
| If not Ongoing, End date (dd MMM yyyy) <input type="text"/>       |                          |                                  |
| <hr/>                                                             |                          |                                  |
| Was this medication taken for solicited event?                    | Yes                      | <input type="radio"/>            |
|                                                                   | No                       | <input checked="" type="radio"/> |
| <hr/>                                                             |                          |                                  |
| Separate Dosage Number (derived)                                  | 1                        |                                  |
| Interval Dosage Unit Number (derived)                             | 1                        |                                  |
| Interval Dosage Definition (derived)                              | 802                      | <input type="radio"/>            |
|                                                                   | 803                      | <input type="radio"/>            |
|                                                                   | 804                      | <input checked="" type="radio"/> |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

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|                                |                                                                                                                                                                                                                                                                                                                                                                                                                          |
|--------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Name of Medication             | OMNICEF<br>[CEFDINIR]                                                                                                                                                                                                                                                                                                                                                                                                    |
| Prophylaxis                    | Yes <input type="radio"/><br>No <input checked="" type="radio"/>                                                                                                                                                                                                                                                                                                                                                         |
| Indication                     | PNEUMONIA                                                                                                                                                                                                                                                                                                                                                                                                                |
| Dose per administration        | 300                                                                                                                                                                                                                                                                                                                                                                                                                      |
| 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 (8)

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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)                           | 15 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 (9)

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|                                |                                                                                                                                                                                                                                                                                                                                                                                                                          |
|--------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Name of Medication             | DOXYCYCLINE HYCLATE                                                                                                                                                                                                                                                                                                                                                                                                      |
| Prophylaxis                    | Yes <input type="radio"/><br>No <input checked="" type="radio"/>                                                                                                                                                                                                                                                                                                                                                         |
| Indication                     | PNEUMONIA                                                                                                                                                                                                                                                                                                                                                                                                                |
| 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 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 (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)                                          | 15 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)                                  | 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 (10)

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|                                |                                                                                                                                                                                                                                                                                                                                                                                                                          |
|--------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Name of Medication             | SODIUM CHLORIDE                                                                                                                                                                                                                                                                                                                                                                                                          |
| Prophylaxis                    | Yes <input type="radio"/><br>No <input checked="" type="radio"/>                                                                                                                                                                                                                                                                                                                                                         |
| Indication                     | DEHYDRATION                                                                                                                                                                                                                                                                                                                                                                                                              |
| Dose per administration        | 100                                                                                                                                                                                                                                                                                                                                                                                                                      |
| Dose unit                      | mg <input type="radio"/><br>ug <input type="radio"/><br>mL <input type="radio"/><br>g <input type="radio"/><br>IU <input type="radio"/><br>tablet <input type="radio"/><br>capsule <input type="radio"/><br>puff <input type="radio"/><br>Other <input checked="" type="radio"/>                                                                                                                                         |
| If dose unit is Other, specify | ML/HR                                                                                                                                                                                                                                                                                                                                                                                                                    |
| Frequency                      | once daily <input type="radio"/><br>twice daily <input type="radio"/><br>three times daily <input type="radio"/><br>four times daily <input type="radio"/><br>every other day <input type="radio"/><br>every week <input type="radio"/><br>every month <input type="radio"/><br>as needed <input type="radio"/><br>once <input type="radio"/><br>unknown <input type="radio"/><br>other <input checked="" type="radio"/> |
| If frequency is Other, specify | CONTINUOUS                                                                                                                                                                                                                                                                                                                                                                                                               |
| Route of administration        | Oral <input type="radio"/><br>Topical <input type="radio"/><br>Subcutaneous <input type="radio"/><br>Transdermal <input type="radio"/><br>Intraocular <input type="radio"/><br>Intramuscular <input type="radio"/>                                                                                                                                                                                                       |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

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|                                                    |                           |                                     |
|----------------------------------------------------|---------------------------|-------------------------------------|
|                                                    | 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 checked="" 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)                           | 10 NOV 2020               |                                     |
| Start date completely unknown                      | False                     |                                     |
| Ongoing?                                           | Yes <input type="radio"/> | No <input checked="" type="radio"/> |
| <hr/>                                              |                           |                                     |
| If not Ongoing, End date (dd MMM yyyy)             |                           | 11 NOV 2020                         |
| 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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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

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|                                      |                                                                                                                                                                                                                                                                                                                                                                                                                          |
|--------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Name of Medication                   | ACETAMINOPHEN                                                                                                                                                                                                                                                                                                                                                                                                            |
| Prophylaxis                          | Yes <input type="radio"/><br>No <input checked="" type="radio"/>                                                                                                                                                                                                                                                                                                                                                         |
| Indication                           | HEADACHE                                                                                                                                                                                                                                                                                                                                                                                                                 |
| 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 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 (11)

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|                                                                   |                                      |                                     |
|-------------------------------------------------------------------|--------------------------------------|-------------------------------------|
|                                                                   | 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 <input type="text"/> |                                      |                                     |
| <hr/>                                                             |                                      |                                     |
| Start date (dd MMM yyyy)                                          | 10 NOV 2020                          |                                     |
| Start date completely unknown                                     | False                                |                                     |
| Ongoing?                                                          | Yes <input type="radio"/>            | No <input checked="" type="radio"/> |
| <hr/>                                                             |                                      |                                     |
| If not Ongoing, End date (dd MMM yyyy) 10 NOV 2020                |                                      |                                     |
| 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 (12)

Generated On: 26 Nov 2020 11:14:36

|                                |                                                                                                                                                                                                                                                                                                                                                                                                                          |
|--------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Name of Medication             | ZOFRAN                                                                                                                                                                                                                                                                                                                                                                                                                   |
| Prophylaxis                    | Yes <input type="radio"/><br>No <input checked="" type="radio"/>                                                                                                                                                                                                                                                                                                                                                         |
| Indication                     | 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 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 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"/>                                                                                                                                                                                                       |



US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:14:36

|                                                    |                                                                                                |
|----------------------------------------------------|------------------------------------------------------------------------------------------------|
| 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 checked="" type="radio"/>                                                               |
| Intravenous Bolus                                  | <input type="radio"/>                                                                          |
| Intravenous Drip                                   | <input type="radio"/>                                                                          |
| Other                                              | <input type="radio"/>                                                                          |
| If route of administration is Other, specify _____ |                                                                                                |
| Start date (dd MMM yyyy)                           | 10 NOV 2020                                                                                    |
| Start date completely unknown                      | False                                                                                          |
| Ongoing?                                           | Yes <input type="radio"/><br>No <input checked="" type="radio"/>                               |
| If not Ongoing, End date (dd MMM yyyy) 10 NOV 2020 |                                                                                                |
| Was this medication taken for solicited event?     | Yes <input type="radio"/><br>No <input checked="" type="radio"/>                               |
| Separate Dosage Number (derived)                   | 1                                                                                              |
| Interval Dosage Unit Number (derived)              | 1                                                                                              |
| Interval Dosage Definition (derived)               | 802 <input type="radio"/><br>803 <input type="radio"/><br>804 <input checked="" type="radio"/> |

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:14:36

|                                      |                                                                                                                                                                                                                                                                                                                                                                                                                          |
|--------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Name of Medication                   | PIPERACILLIN-TAZOBACTAM                                                                                                                                                                                                                                                                                                                                                                                                  |
| Prophylaxis                          | Yes <input type="radio"/><br>No <input checked="" type="radio"/>                                                                                                                                                                                                                                                                                                                                                         |
| Indication                           | PNEUMONIA                                                                                                                                                                                                                                                                                                                                                                                                                |
| Dose per administration              | 3.375                                                                                                                                                                                                                                                                                                                                                                                                                    |
| Dose unit                            | mg <input type="radio"/><br>ug <input type="radio"/><br>mL <input type="radio"/><br>g <input checked="" 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 checked="" 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 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"/>                                                                                                                                                                                                       |

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:14:36

|                                                    |                                                                                                |
|----------------------------------------------------|------------------------------------------------------------------------------------------------|
| 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 checked="" type="radio"/>                                                               |
| Intravenous Bolus                                  | <input type="radio"/>                                                                          |
| Intravenous Drip                                   | <input type="radio"/>                                                                          |
| Other                                              | <input type="radio"/>                                                                          |
| If route of administration is Other, specify _____ |                                                                                                |
| Start date (dd MMM yyyy)                           | 12 NOV 2020                                                                                    |
| Start date completely unknown                      | False                                                                                          |
| Ongoing?                                           | Yes <input type="radio"/><br>No <input checked="" type="radio"/>                               |
| If not Ongoing, End date (dd MMM yyyy)             | 15 NOV 2020                                                                                    |
| Was this medication taken for solicited event?     | Yes <input type="radio"/><br>No <input checked="" type="radio"/>                               |
| Separate Dosage Number (derived)                   | 4                                                                                              |
| Interval Dosage Unit Number (derived)              | 1                                                                                              |
| Interval Dosage Definition (derived)               | 802 <input type="radio"/><br>803 <input type="radio"/><br>804 <input checked="" type="radio"/> |

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:14:36

|                                |                                                                                                                                                                                                                                                                                                                                                                                                                          |
|--------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Name of Medication             | VANCOMYCIN                                                                                                                                                                                                                                                                                                                                                                                                               |
| Prophylaxis                    | Yes <input type="radio"/><br>No <input checked="" type="radio"/>                                                                                                                                                                                                                                                                                                                                                         |
| Indication                     | PNEUMONIA                                                                                                                                                                                                                                                                                                                                                                                                                |
| Dose per administration        | 1500                                                                                                                                                                                                                                                                                                                                                                                                                     |
| 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 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"/>                                                                                                                                                                                                       |

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:14:36

|                                                    |                                                                                                         |
|----------------------------------------------------|---------------------------------------------------------------------------------------------------------|
| 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 checked="" type="checkbox"/>                                                                     |
| Intravenous Bolus                                  | <input type="checkbox"/>                                                                                |
| Intravenous Drip                                   | <input type="checkbox"/>                                                                                |
| Other                                              | <input type="checkbox"/>                                                                                |
| If route of administration is Other, specify _____ |                                                                                                         |
| Start date (dd MMM yyyy)                           | 13 NOV 2020                                                                                             |
| Start date completely unknown                      | False                                                                                                   |
| Ongoing?                                           | Yes <input type="checkbox"/><br>No <input checked="" type="checkbox"/>                                  |
| If not Ongoing, End date (dd MMM yyyy)             | 15 NOV 2020                                                                                             |
| Was this medication taken for solicited event?     | Yes <input type="checkbox"/><br>No <input checked="" type="checkbox"/>                                  |
| Separate Dosage Number (derived)                   | 1                                                                                                       |
| Interval Dosage Unit Number (derived)              | 1                                                                                                       |
| Interval Dosage Definition (derived)               | 802 <input type="checkbox"/><br>803 <input type="checkbox"/><br>804 <input checked="" type="checkbox"/> |

US3762161

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures Summary**

**Generated On: 26 Nov 2020 11:14:36**

---

Were any concomitant procedures performed?

Yes ☐

No ☐

---

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

---

US3762161

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 11:14:36

---

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

---

US3762161

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 11:14:36

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 ☐



US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:14:36

|                                                                |                                                                  |
|----------------------------------------------------------------|------------------------------------------------------------------|
| SAEID                                                          | USA-US130-2020-MRNA-1273-P301000001                              |
| 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 checked="" type="radio"/><br>No <input 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                                      | JOHN                                                             |
| Investigator's Last Name                                       | SANDERS                                                          |
| Site Address: Street                                           | 100 MEDICAL CENTER BLVD                                          |
| Site Address: City                                             | WINSTON-SALEM                                                    |
| Site Address: State                                            | NC                                                               |
| Site Address: Postal Code                                      | 27157                                                            |
| Investigator Country                                           | US                                                               |
| E2B Transmit Flag (Derived/Hidden)                             | 5                                                                |

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 11:14:36

|                                                                                                                                                                                               |                                                                  |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------|
| SAEID                                                                                                                                                                                         | USA-US130-2020-MRNA-1273-P301000001                              |
| 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 checked="" type="radio"/><br>No <input 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                                                                                                                                                                     | JOHN                                                             |
| Investigator's Last Name                                                                                                                                                                      | SANDERS                                                          |
| Site Address: Street                                                                                                                                                                          | 100 MEDICAL CENTER BLVD                                          |
| Site Address: City                                                                                                                                                                            | WINSTON-SALEM                                                    |
| Site Address: State                                                                                                                                                                           | NC                                                               |
| Site Address: Postal Code                                                                                                                                                                     | 27157                                                            |
| Investigator Country                                                                                                                                                                          | US                                                               |
| E2B Transmit Flag (Derived/Hidden)                                                                                                                                                            | 5                                                                |
| Date of submission (Pre-filled from custom function)                                                                                                                                          | 12/NOV/2020 15:36                                                |
| 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                                                             |

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 11:14:36

|                                                                                                                                                                                               |                                                                  |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------|
| SAEID                                                                                                                                                                                         | USA-US130-2020-MRNA-1273-P301000001                              |
| 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 checked="" type="radio"/><br>No <input 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                                                                                                                                                                     | JOHN                                                             |
| Investigator's Last Name                                                                                                                                                                      | SANDERS                                                          |
| Site Address: Street                                                                                                                                                                          | 100 MEDICAL CENTER BLVD                                          |
| Site Address: City                                                                                                                                                                            | WINSTON-SALEM                                                    |
| Site Address: State                                                                                                                                                                           | NC                                                               |
| Site Address: Postal Code                                                                                                                                                                     | 27157                                                            |
| Investigator Country                                                                                                                                                                          | US                                                               |
| E2B Transmit Flag (Derived/Hidden)                                                                                                                                                            | 5                                                                |
| Date of submission (Pre-filled from custom function)                                                                                                                                          | 16/NOV/2020 09:49                                                |
| 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                                                             |

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 11:14:36

|                                                                                                                                                                                               |                                                                  |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------|
| SAEID                                                                                                                                                                                         | USA-US130-2020-MRNA-1273-P301000001                              |
| 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 checked="" type="radio"/><br>No <input 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                                                                                                                                                                     | JOHN                                                             |
| Investigator's Last Name                                                                                                                                                                      | SANDERS                                                          |
| Site Address: Street                                                                                                                                                                          | 100 MEDICAL CENTER BLVD                                          |
| Site Address: City                                                                                                                                                                            | WINSTON-SALEM                                                    |
| Site Address: State                                                                                                                                                                           | NC                                                               |
| Site Address: Postal Code                                                                                                                                                                     | 27157                                                            |
| Investigator Country                                                                                                                                                                          | US                                                               |
| E2B Transmit Flag (Derived/Hidden)                                                                                                                                                            | 5                                                                |
| Date of submission (Pre-filled from custom function)                                                                                                                                          | 18/NOV/2020 15:00                                                |
| 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                                                             |

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form (4)

Generated On: 26 Nov 2020 11:14:36

|                                                                                                                                                                                               |                                                                  |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------|
| SAEID                                                                                                                                                                                         | USA-US130-2020-MRNA-1273-P301000001                              |
| 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 checked="" type="radio"/><br>No <input 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                                                                                                                                                                     | JOHN                                                             |
| Investigator's Last Name                                                                                                                                                                      | SANDERS                                                          |
| Site Address: Street                                                                                                                                                                          | 100 MEDICAL CENTER BLVD                                          |
| Site Address: City                                                                                                                                                                            | WINSTON-SALEM                                                    |
| Site Address: State                                                                                                                                                                           | NC                                                               |
| Site Address: Postal Code                                                                                                                                                                     | 27157                                                            |
| Investigator Country                                                                                                                                                                          | US                                                               |
| E2B Transmit Flag (Derived/Hidden)                                                                                                                                                            | 5                                                                |
| Date of submission (Pre-filled from custom function)                                                                                                                                          | 19/NOV/2020 13:36                                                |
| 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                                                             |

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form (5)

Generated On: 26 Nov 2020 11:14:36

|                                                                                                                                                                                               |                                                                  |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------|
| SAEID                                                                                                                                                                                         | USA-US130-2020-MRNA-1273-P301000001                              |
| 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 checked="" type="radio"/><br>No <input 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                                                                                                                                                                     | JOHN                                                             |
| Investigator's Last Name                                                                                                                                                                      | SANDERS                                                          |
| Site Address: Street                                                                                                                                                                          | 100 MEDICAL CENTER BLVD                                          |
| Site Address: City                                                                                                                                                                            | WINSTON-SALEM                                                    |
| Site Address: State                                                                                                                                                                           | NC                                                               |
| Site Address: Postal Code                                                                                                                                                                     | 27157                                                            |
| Investigator Country                                                                                                                                                                          | US                                                               |
| E2B Transmit Flag (Derived/Hidden)                                                                                                                                                            | 5                                                                |
| Date of submission (Pre-filled from custom function)                                                                                                                                          | 20/NOV/2020 10:40                                                |
| 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

US3762161 (Prod: Wake Forest University Health Sciences)

**US3762161**

**Form: Participant Creation**

**Generated On: 26 Nov 2020 11:14:36**

[Participant ID](#)

| Audit                    | User                                            | Time (GMT)           |
|--------------------------|-------------------------------------------------|----------------------|
| User entered 'US3762161' | RWS_ENDPOINT<br>ENDPOINT (b) (4)<br><div></div> | 02 Sep 2020 18:29:42 |



US3762161

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:14:36

[Was this visit performed?](#)

| Audit                  | User                     | Time (GMT)           |
|------------------------|--------------------------|----------------------|
| User entered 'Yes (Y)' | Samantha Wheeler (b) (4) | 02 Sep 2020 19:21:07 |
|                        | (b) (4)                  |                      |

US3762161

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:14:36

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

| Audit                      | User                                            | Time (GMT)           |
|----------------------------|-------------------------------------------------|----------------------|
| User entered '02 SEP 2020' | RWS_ENDPOINT<br>ENDPOINT (b) (4)<br><div></div> | 02 Sep 2020 18:29:43 |

US3762161

**Folder: Screening**

**Form: Visit Date**

**Generated On: 26 Nov 2020 11:14:36**

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

| Audit                          | User                     | Time (GMT)           |
|--------------------------------|--------------------------|----------------------|
| User entered 'Clinic (Clinic)' | Samantha Wheeler (b) (4) | 02 Sep 2020 19:21:07 |
|                                | (b) (4)                  |                      |

**US3762161**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 26 Nov 2020 11:14:36**

[Folder OID](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'SCRN' | System | 02 Sep 2020 19:21:07 |

US3762161

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:14:36

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

| Audit                      | User                                           | Time (GMT)           |
|----------------------------|------------------------------------------------|----------------------|
| User entered (b) (6) 1946' | RWS_ENDPOINT<br>ENDPOINT (b) (4)<br>[REDACTED] | 02 Sep 2020 18:29:44 |

US3762161

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:14:36

[Age](#)

| Audit                                                                          | User                     | Time (GMT)           |
|--------------------------------------------------------------------------------|--------------------------|----------------------|
| User closed query 'Per CDM: Please complete the form' (Site from DM).          | (b) (4), (b) (6)         | 21 Sep 2020 10:34:37 |
| Query 'Per CDM: Please complete the form' answered with 'Done' (Site from DM). | Samantha Wheeler (b) (4) | 21 Sep 2020 01:09:42 |
| User entered '74'                                                              | (b) (4)                  |                      |
|                                                                                | Kaitlyn Van Leuvan       | 09 Sep 2020 20:26:03 |
| User opened query 'Per CDM: Please complete the form' (Site from DM).          | (b) (4)                  |                      |
|                                                                                | (b) (4), (b) (6)         | 08 Sep 2020 07:29:37 |

US3762161

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 11:14:36**

[Age Units](#)

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| User entered 'YEARS' | System | 09 Sep 2020 20:26:03 |

US3762161

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 11:14:36**

[Age \(Derived\)](#)

| Audit             | User   | Time (GMT)           |
|-------------------|--------|----------------------|
| User entered '74' | System | 02 Sep 2020 19:21:26 |



US3762161

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:14:36

Sex

| Audit                   | User                          | Time (GMT)           |
|-------------------------|-------------------------------|----------------------|
| User entered 'Male (M)' | Kaitlyn Van Leuvan<br>(b) (4) | 09 Sep 2020 20:26:03 |

US3762161

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:14:36

[Ethnicity](#)

| Audit                                                          | User                          | Time (GMT)           |
|----------------------------------------------------------------|-------------------------------|----------------------|
| User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)' | Kaitlyn Van Leuvan<br>(b) (4) | 09 Sep 2020 20:26:03 |

US3762161

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:14:36

White

| Audit            | User                          | Time (GMT)           |
|------------------|-------------------------------|----------------------|
| User entered '1' | Kaitlyn Van Leuvan<br>(b) (4) | 09 Sep 2020 20:26:03 |

US3762161

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:14:36

[Black](#)

| Audit            | User                          | Time (GMT)           |
|------------------|-------------------------------|----------------------|
| User entered '0' | Kaitlyn Van Leuvan<br>(b) (4) | 09 Sep 2020 20:26:03 |

US3762161

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:14:36

[Asian](#)

| Audit            | User                          | Time (GMT)           |
|------------------|-------------------------------|----------------------|
| User entered '0' | Kaitlyn Van Leuvan<br>(b) (4) | 09 Sep 2020 20:26:03 |

US3762161

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 11:14:36**

[American Indian or Alaska Native](#)

| Audit            | User                          | Time (GMT)           |
|------------------|-------------------------------|----------------------|
| User entered '0' | Kaitlyn Van Leuvan<br>(b) (4) | 09 Sep 2020 20:26:03 |

US3762161

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 11:14:36**

[Native Hawaiian or other Pacific Islander](#)

| Audit            | User                          | Time (GMT)           |
|------------------|-------------------------------|----------------------|
| User entered '0' | Kaitlyn Van Leuvan<br>(b) (4) | 09 Sep 2020 20:26:03 |

US3762161

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 11:14:36**

[Other](#)

| Audit            | User                          | Time (GMT)           |
|------------------|-------------------------------|----------------------|
| User entered '0' | Kaitlyn Van Leuvan<br>(b) (4) | 09 Sep 2020 20:26:03 |



US3762161

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 11:14:36**

[If race is Other, specify](#)

| Audit               | User                          | Time (GMT)           |
|---------------------|-------------------------------|----------------------|
| User entered empty. | Kaitlyn Van Leuvan<br>(b) (4) | 09 Sep 2020 20:26:03 |

US3762161

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:14:36

Unknown

| Audit            | User                          | Time (GMT)           |
|------------------|-------------------------------|----------------------|
| User entered '0' | Kaitlyn Van Leuvan<br>(b) (4) | 09 Sep 2020 20:26:03 |

US3762161

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:14:36

[Not reported](#)

| Audit            | User                          | Time (GMT)           |
|------------------|-------------------------------|----------------------|
| User entered '0' | Kaitlyn Van Leuvan<br>(b) (4) | 09 Sep 2020 20:26:03 |

US3762161

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 11:14:36**

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

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| User entered '02 Sep 2020' | Samantha Wheeler (b) (4) | 02 Sep 2020 19:21:26 |
|                            | (b) (4)                  |                      |

**US3762161**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 11:14:36**

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

| Audit                   | User   | Time (GMT)           |
|-------------------------|--------|----------------------|
| User entered 'Sep 2020' | System | 02 Sep 2020 19:21:26 |

US3762161

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 11:14:36**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '2020' | System | 02 Sep 2020 19:21:26 |

US3762161

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 11:14:36**

[Protocol Version](#)

| Audit                          | User                     | Time (GMT)           |
|--------------------------------|--------------------------|----------------------|
| User entered 'Amendment 3 (3)' | Samantha Wheeler (b) (4) | 02 Sep 2020 19:21:26 |
|                                | (b) (4)                  |                      |

US3762161

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 11:14:36**

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

| Audit                  | User                     | Time (GMT)           |
|------------------------|--------------------------|----------------------|
| User entered 'Yes (Y)' | Samantha Wheeler (b) (4) | 02 Sep 2020 19:21:26 |
|                        | (b) (4)                  |                      |



US3762161

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 11:14:36**

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

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| User entered empty. | Samantha Wheeler (b) (4) | 02 Sep 2020 19:21:26 |
|                     | (b) (4)                  |                      |

US3762161

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 11:14:36**

If reason for screen fail is Other, specify

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| User entered empty. | Samantha Wheeler (b) (4) | 02 Sep 2020 19:21:26 |
|                     | (b) (4)                  |                      |

US3762161

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 11:14:36**

[Was this participant screened previously?](#)

| Audit                 | User                                | Time (GMT)           |
|-----------------------|-------------------------------------|----------------------|
| User entered 'No (N)' | Samantha Wheeler (b) (4)<br>(b) (4) | 02 Sep 2020 19:21:26 |

US3762161

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 11:14:36**

[If Yes, previous participant number](#)

| Audit               | User                                           | Time (GMT)           |
|---------------------|------------------------------------------------|----------------------|
| User entered empty. | RWS_ENDPOINT<br>ENDPOINT (b) (4)<br>[REDACTED] | 02 Sep 2020 18:29:43 |

US3762161

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 11:14:36**

[Enrollment Trigger](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 02 Sep 2020 19:21:55 |

US3762161

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 11:14:36

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

| Audit                  | User                     | Time (GMT)           |
|------------------------|--------------------------|----------------------|
| User entered 'Yes (Y)' | Samantha Wheeler (b) (4) | 02 Sep 2020 19:21:55 |
|                        | (b) (4)                  |                      |

US3762161

**Folder: Screening**

**Form: Medical History Summary**

**Generated On: 26 Nov 2020 11:14:36**

[Were any significant conditions reported?](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 28 Oct 2020 18:50:06 |
|                        |                  |                      |

US3762161

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:14:36

[Condition](#)

| Audit                                                                                                                                                                                                | User                 | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|----------------------|
| User coded data point as SOC: Eye disorders, HLGT: Anterior eye structural change, deposit and degeneration, HLT: Cataract conditions, PT: Cataract, LLT: Bilateral cataracts - version MedDRA\23.0. | Coder Import (b) (4) | 29 Oct 2020 19:55:10 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.                                                                                                          | Coder Import (b) (4) | 29 Oct 2020 19:55:10 |
| Data point term sent to Coder                                                                                                                                                                        | System               | 28 Oct 2020 18:57:27 |
| User entered 'Cataracts - Bilateral'                                                                                                                                                                 | (b) (4), (b) (6)     | 28 Oct 2020 18:56:43 |



US3762161

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 11:14:36**

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

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| User entered 'UN UNK 2016' | (b) (4), (b) (6) | 28 Oct 2020 18:56:43 |
|                            |                  |                      |

US3762161

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 11:14:36**

[Start date completely unknown](#)

| Audit            | User             | Time (GMT)           |
|------------------|------------------|----------------------|
| User entered '0' | (b) (4), (b) (6) | 28 Oct 2020 18:56:43 |
|                  |                  |                      |

US3762161

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 11:14:36**

[Condition ongoing at study entry](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| User entered 'No (N)' | (b) (4), (b) (6) | 28 Oct 2020 18:56:43 |
|                       |                  |                      |

US3762161

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 11:14:36**

If No, please specify the stop date (dd MMM yyyy)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| User entered 'UN UNK 2017' | (b) (4), (b) (6) | 28 Oct 2020 18:56:43 |
|                            |                  |                      |

US3762161

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:14:36

[Stop date completely unknown](#)

| Audit            | User             | Time (GMT)           |
|------------------|------------------|----------------------|
| User entered '0' | (b) (4), (b) (6) | 28 Oct 2020 18:56:43 |
|                  |                  |                      |

US3762161

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 11:14:36**

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

| Audit                   | User   | Time (GMT)           |
|-------------------------|--------|----------------------|
| User entered 'Jan 2016' | System | 28 Oct 2020 18:56:43 |

**US3762161**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 11:14:36**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '2016' | System | 28 Oct 2020 18:56:43 |

US3762161

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 11:14:36**

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

| Audit                   | User   | Time (GMT)           |
|-------------------------|--------|----------------------|
| User entered 'Jan 2017' | System | 28 Oct 2020 18:56:43 |



**US3762161**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 11:14:36**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '2017' | System | 28 Oct 2020 18:56:43 |

US3762161

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:14:36

[Condition](#)

| Audit                                                                                                                                                                                                                               | User                                 | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------|----------------------|
| User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Diabetes mellitus (incl subtypes), PT: Diabetes mellitus, LLT: Diabetes - version MedDRA\\23.0. | Coder Import (b) (4)<br>(b) (4)      | 29 Oct 2020 19:55:10 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.                                                                                                                                        | Coder Import (b) (4)<br>(b) (4)      | 29 Oct 2020 19:55:10 |
| Data point term sent to Coder                                                                                                                                                                                                       | System                               | 28 Oct 2020 18:57:27 |
| User entered 'Diabetes'                                                                                                                                                                                                             | (b) (4), (b) (6)<br>(b) (4), (b) (6) | 28 Oct 2020 18:57:01 |

US3762161

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 11:14:36**

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

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| User entered 'UN UNK 1998' | (b) (4), (b) (6) | 28 Oct 2020 18:57:01 |
|                            |                  |                      |

US3762161

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 11:14:36**

[Start date completely unknown](#)

| Audit            | User             | Time (GMT)           |
|------------------|------------------|----------------------|
| User entered '0' | (b) (4), (b) (6) | 28 Oct 2020 18:57:01 |
|                  |                  |                      |

US3762161

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 11:14:36**

[Condition ongoing at study entry](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 28 Oct 2020 18:57:01 |
|                        |                  |                      |

US3762161

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 11:14:36**

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 28 Oct 2020 18:57:01 |
|                     |                  |                      |

US3762161

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 11:14:36**

[Stop date completely unknown](#)

| Audit            | User             | Time (GMT)           |
|------------------|------------------|----------------------|
| User entered '0' | (b) (4), (b) (6) | 28 Oct 2020 18:57:01 |
|                  |                  |                      |

**US3762161**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 11:14:36**

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

| Audit                   | User   | Time (GMT)           |
|-------------------------|--------|----------------------|
| User entered 'Jan 1998' | System | 28 Oct 2020 18:57:01 |



US3762161

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 11:14:36**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '1998' | System | 28 Oct 2020 18:57:01 |

US3762161

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 11:14:36**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 28 Oct 2020 18:57:01 |

**US3762161**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 11:14:36**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 28 Oct 2020 18:57:01 |

US3762161

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:14:36

[Condition](#)

| Audit                                                                                                                                                                         | User                 | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|----------------------|
| User coded data point as SOC: Investigations, HLGT: Lipid analyses, HLT: Cholesterol analyses, PT: Blood cholesterol increased, LLT: High cholesterol - version MedDRA\\23.0. | Coder Import (b) (4) | 29 Oct 2020 19:55:12 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.                                                                                  | Coder Import (b) (4) | 29 Oct 2020 19:55:12 |
| Data point term sent to Coder                                                                                                                                                 | System               | 28 Oct 2020 18:57:29 |
| User entered 'High Cholesterol'                                                                                                                                               | (b) (4), (b) (6)     | 28 Oct 2020 18:57:28 |

US3762161

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 11:14:36**

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

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| User entered 'UN UNK 2000' | (b) (4), (b) (6) | 28 Oct 2020 18:57:28 |
|                            |                  |                      |

US3762161

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 11:14:36**

[Start date completely unknown](#)

| Audit            | User             | Time (GMT)           |
|------------------|------------------|----------------------|
| User entered '0' | (b) (4), (b) (6) | 28 Oct 2020 18:57:28 |
|                  |                  |                      |

US3762161

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 11:14:36**

[Condition ongoing at study entry](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 28 Oct 2020 18:57:28 |
|                        |                  |                      |

US3762161

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 11:14:36**

If No, please specify the stop date (dd MMM yyyy)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 28 Oct 2020 18:57:28 |
|                     |                  |                      |



US3762161

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 11:14:36**

[Stop date completely unknown](#)

| Audit            | User             | Time (GMT)           |
|------------------|------------------|----------------------|
| User entered '0' | (b) (4), (b) (6) | 28 Oct 2020 18:57:28 |
|                  |                  |                      |

**US3762161**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 11:14:36**

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

| Audit                   | User   | Time (GMT)           |
|-------------------------|--------|----------------------|
| User entered 'Jan 2000' | System | 28 Oct 2020 18:57:28 |

US3762161

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 11:14:36**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '2000' | System | 28 Oct 2020 18:57:28 |

**US3762161**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 11:14:36**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 28 Oct 2020 18:57:28 |

**US3762161**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 11:14:36**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 28 Oct 2020 18:57:28 |

US3762161

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:14:36

Condition

| Audit                                                                                                                                                                                            | User                 | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|----------------------|
| User coded data point as SOC: Nervous system disorders, HLGT: Neurological disorders NEC, HLT: Paraesthesias and dysaesthesias, PT: Hypoaesthesia, LLT: Numbness in feet - version MedDRA\\23.0. | Coder Import (b) (4) | 29 Oct 2020 19:55:32 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.                                                                                                     | Coder Import (b) (4) | 29 Oct 2020 19:55:32 |
| Data point term sent to Coder                                                                                                                                                                    | System               | 28 Oct 2020 18:58:29 |
| User entered 'Numbness in Feet'                                                                                                                                                                  | (b) (4), (b) (6)     | 28 Oct 2020 18:57:57 |

US3762161

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 26 Nov 2020 11:14:36**

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

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| User entered 'UN UNK 2010' | (b) (4), (b) (6) | 28 Oct 2020 18:57:57 |
|                            |                  |                      |

US3762161

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 26 Nov 2020 11:14:36**

[Start date completely unknown](#)

| Audit            | User             | Time (GMT)           |
|------------------|------------------|----------------------|
| User entered '0' | (b) (4), (b) (6) | 28 Oct 2020 18:57:57 |
|                  |                  |                      |



US3762161

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 26 Nov 2020 11:14:36**

[Condition ongoing at study entry](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 28 Oct 2020 18:57:57 |
|                        |                  |                      |

US3762161

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 26 Nov 2020 11:14:36**

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 28 Oct 2020 18:57:57 |
|                     |                  |                      |

US3762161

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:14:36

[Stop date completely unknown](#)

| Audit            | User             | Time (GMT)           |
|------------------|------------------|----------------------|
| User entered '0' | (b) (4), (b) (6) | 28 Oct 2020 18:57:57 |
|                  |                  |                      |

US3762161

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 26 Nov 2020 11:14:36**

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

| Audit                   | User   | Time (GMT)           |
|-------------------------|--------|----------------------|
| User entered 'Jan 2010' | System | 28 Oct 2020 18:57:57 |

**US3762161**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 26 Nov 2020 11:14:36**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '2010' | System | 28 Oct 2020 18:57:57 |

**US3762161**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 26 Nov 2020 11:14:36**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 28 Oct 2020 18:57:57 |

**US3762161**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 26 Nov 2020 11:14:36**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 28 Oct 2020 18:57:57 |

US3762161

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:14:36

[Condition](#)

| Audit                                                                                                                                                                                | User                 | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|----------------------|
| User coded data point as SOC: Nervous system disorders, HLGT: Movement disorders (incl parkinsonism), HLT: Tremor (excl congenital), PT: Tremor, LLT: Tremor - version MedDRA\\23.0. | Coder Import (b) (4) | 29 Oct 2020 19:55:21 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.                                                                                         | Coder Import (b) (4) | 29 Oct 2020 19:55:21 |
| Data point term sent to Coder                                                                                                                                                        | System               | 28 Oct 2020 18:58:30 |
| User entered 'Tremors'                                                                                                                                                               | (b) (4), (b) (6)     | 28 Oct 2020 18:58:17 |



US3762161

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 26 Nov 2020 11:14:36**

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

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| User entered 'UN UNK 2011' | (b) (4), (b) (6) | 28 Oct 2020 18:58:17 |
|                            |                  |                      |

US3762161

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 26 Nov 2020 11:14:36**

[Start date completely unknown](#)

| Audit            | User             | Time (GMT)           |
|------------------|------------------|----------------------|
| User entered '0' | (b) (4), (b) (6) | 28 Oct 2020 18:58:17 |
|                  |                  |                      |

US3762161

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 26 Nov 2020 11:14:36**

[Condition ongoing at study entry](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 28 Oct 2020 18:58:17 |
|                        |                  |                      |

US3762161

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 26 Nov 2020 11:14:36**

If No, please specify the stop date (dd MMM yyyy)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 28 Oct 2020 18:58:17 |
|                     |                  |                      |

US3762161

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:14:36

[Stop date completely unknown](#)

| Audit            | User             | Time (GMT)           |
|------------------|------------------|----------------------|
| User entered '0' | (b) (4), (b) (6) | 28 Oct 2020 18:58:17 |
|                  |                  |                      |

**US3762161**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 26 Nov 2020 11:14:36**

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

| Audit                   | User   | Time (GMT)           |
|-------------------------|--------|----------------------|
| User entered 'Jan 2011' | System | 28 Oct 2020 18:58:17 |

US3762161

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 26 Nov 2020 11:14:36**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '2011' | System | 28 Oct 2020 18:58:17 |

US3762161

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 26 Nov 2020 11:14:36**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 28 Oct 2020 18:58:17 |



US3762161

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 26 Nov 2020 11:14:36**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 28 Oct 2020 18:58:17 |

US3762161

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:14:36

[Condition](#)

| Audit                                                                                                                                                                                           | User                 | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|----------------------|
| User coded data point as SOC: Nervous system disorders, HLGT: Peripheral neuropathies, HLT: Chronic polyneuropathies, PT: Diabetic neuropathy, LLT: Diabetic neuropathy - version MedDRA\\23.0. | Coder Import (b) (4) | 29 Oct 2020 19:55:35 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.                                                                                                    | Coder Import (b) (4) | 29 Oct 2020 19:55:35 |
| Data point term sent to Coder                                                                                                                                                                   | System               | 28 Oct 2020 18:59:30 |
| User entered 'Diabetic Neuropathy'                                                                                                                                                              | (b) (4), (b) (6)     | 28 Oct 2020 18:58:44 |

US3762161

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 26 Nov 2020 11:14:36**

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

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| User entered 'UN UNK 1998' | (b) (4), (b) (6) | 28 Oct 2020 18:58:44 |
|                            |                  |                      |

US3762161

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:14:36

[Start date completely unknown](#)

| Audit            | User             | Time (GMT)           |
|------------------|------------------|----------------------|
| User entered '0' | (b) (4), (b) (6) | 28 Oct 2020 18:58:44 |
|                  |                  |                      |

US3762161

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 26 Nov 2020 11:14:36**

[Condition ongoing at study entry](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 28 Oct 2020 18:58:44 |
|                        |                  |                      |

US3762161

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 26 Nov 2020 11:14:36**

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 28 Oct 2020 18:58:44 |
|                     |                  |                      |

US3762161

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 26 Nov 2020 11:14:36**

[Stop date completely unknown](#)

| Audit            | User             | Time (GMT)           |
|------------------|------------------|----------------------|
| User entered '0' | (b) (4), (b) (6) | 28 Oct 2020 18:58:44 |
|                  |                  |                      |

US3762161

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 26 Nov 2020 11:14:36**

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

| Audit                   | User   | Time (GMT)           |
|-------------------------|--------|----------------------|
| User entered 'Jan 1998' | System | 28 Oct 2020 18:58:44 |



**US3762161**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 26 Nov 2020 11:14:36**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '1998' | System | 28 Oct 2020 18:58:44 |

**US3762161**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 26 Nov 2020 11:14:36**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 28 Oct 2020 18:58:44 |

**US3762161**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 26 Nov 2020 11:14:36**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 28 Oct 2020 18:58:44 |

US3762161

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:14:36

[Condition](#)

| Audit                                                                                                                                                                                                                                              | User                            | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------|----------------------|
| User coded data point as SOC: Nervous system disorders, HLGT: Central nervous system vascular disorders, HLT: Central nervous system haemorrhages and cerebrovascular accidents, PT: Cerebrovascular accident, LLT: Stroke - version MedDRA\\23.0. | Coder Import (b) (4)<br>(b) (4) | 10 Nov 2020 13:37:31 |
| User coded data point as Term Coded data point by User: (b) (6) version MedDRA\\23.0.                                                                                                                                                              | Coder Import (b) (4)<br>(b) (4) | 10 Nov 2020 13:37:31 |
| Data point term sent to Coder                                                                                                                                                                                                                      | System                          | 28 Oct 2020 18:59:31 |
| User entered 'Stroke - Cerebellum'                                                                                                                                                                                                                 | (b) (4), (b) (6)<br>(b) (4)     | 28 Oct 2020 18:59:22 |

US3762161

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 26 Nov 2020 11:14:36**

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

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| User entered 'UN UNK 2006' | (b) (4), (b) (6) | 28 Oct 2020 18:59:22 |
|                            |                  |                      |

US3762161

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:14:36

[Start date completely unknown](#)

| Audit            | User             | Time (GMT)           |
|------------------|------------------|----------------------|
| User entered '0' | (b) (4), (b) (6) | 28 Oct 2020 18:59:22 |
|                  |                  |                      |

US3762161

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 26 Nov 2020 11:14:36**

[Condition ongoing at study entry](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| User entered 'No (N)' | (b) (4), (b) (6) | 28 Oct 2020 18:59:22 |
|                       |                  |                      |

US3762161

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 26 Nov 2020 11:14:36**

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

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| User entered 'UN UNK 2006' | (b) (4), (b) (6) | 28 Oct 2020 18:59:22 |
|                            |                  |                      |



US3762161

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 26 Nov 2020 11:14:36**

[Stop date completely unknown](#)

| Audit            | User             | Time (GMT)           |
|------------------|------------------|----------------------|
| User entered '0' | (b) (4), (b) (6) | 28 Oct 2020 18:59:22 |
|                  |                  |                      |

**US3762161**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 26 Nov 2020 11:14:36**

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

| Audit                   | User   | Time (GMT)           |
|-------------------------|--------|----------------------|
| User entered 'Jan 2006' | System | 28 Oct 2020 18:59:22 |

**US3762161**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 26 Nov 2020 11:14:36**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '2006' | System | 28 Oct 2020 18:59:22 |

**US3762161**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 26 Nov 2020 11:14:36**

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

| Audit                   | User   | Time (GMT)           |
|-------------------------|--------|----------------------|
| User entered 'Jan 2006' | System | 28 Oct 2020 18:59:22 |

**US3762161**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 26 Nov 2020 11:14:36**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '2006' | System | 28 Oct 2020 18:59:22 |

US3762161

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:14:36

Condition

| Audit                                                                                                                                                                                            | User                 | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|----------------------|
| User coded data point as SOC: Cardiac disorders, HLGT: Coronary artery disorders, HLT: Ischaemic coronary artery disorders, PT: Myocardial infarction, LLT: Heart attack - version MedDRA\\23.0. | Coder Import (b) (4) | 29 Oct 2020 19:55:36 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.                                                                                                     | Coder Import (b) (4) | 29 Oct 2020 19:55:36 |
| Data point term sent to Coder                                                                                                                                                                    | System               | 28 Oct 2020 19:00:31 |
| User entered 'Heart Attack'                                                                                                                                                                      | (b) (4), (b) (6)     | 28 Oct 2020 19:00:05 |

US3762161

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 26 Nov 2020 11:14:36**

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

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| User entered 'UN UNK 2007' | (b) (4), (b) (6) | 28 Oct 2020 19:00:05 |
|                            |                  |                      |

US3762161

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 26 Nov 2020 11:14:36**

[Start date completely unknown](#)

| Audit            | User             | Time (GMT)           |
|------------------|------------------|----------------------|
| User entered '0' | (b) (4), (b) (6) | 28 Oct 2020 19:00:05 |
|                  |                  |                      |



US3762161

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 26 Nov 2020 11:14:36**

[Condition ongoing at study entry](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| User entered 'No (N)' | (b) (4), (b) (6) | 28 Oct 2020 19:00:05 |
|                       |                  |                      |

US3762161

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 26 Nov 2020 11:14:36**

If No, please specify the stop date (dd MMM yyyy)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| User entered 'UN UNK 2007' | (b) (4), (b) (6) | 28 Oct 2020 19:00:05 |
|                            |                  |                      |

US3762161

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:14:36

[Stop date completely unknown](#)

| Audit            | User             | Time (GMT)           |
|------------------|------------------|----------------------|
| User entered '0' | (b) (4), (b) (6) | 28 Oct 2020 19:00:05 |
|                  |                  |                      |

US3762161

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 26 Nov 2020 11:14:36**

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

| Audit                   | User   | Time (GMT)           |
|-------------------------|--------|----------------------|
| User entered 'Jan 2007' | System | 28 Oct 2020 19:00:05 |

US3762161

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 26 Nov 2020 11:14:36**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '2007' | System | 28 Oct 2020 19:00:05 |

US3762161

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 26 Nov 2020 11:14:36**

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

| Audit                   | User   | Time (GMT)           |
|-------------------------|--------|----------------------|
| User entered 'Jan 2007' | System | 28 Oct 2020 19:00:05 |

US3762161

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 26 Nov 2020 11:14:36**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '2007' | System | 28 Oct 2020 19:00:05 |

US3762161

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:14:36

[Condition](#)

| Audit                                                                                                                                                                | User                                 | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------|----------------------|
| User coded data point as SOC: Renal and urinary disorders, HLGT: Urolithiasis, HLT: Renal lithiasis, PT: Nephrolithiasis, LLT: Kidney stones - version MedDRA\\23.0. | Coder Import (b) (4)<br>(b) (4)      | 29 Oct 2020 19:55:38 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.                                                                         | Coder Import (b) (4)<br>(b) (4)      | 29 Oct 2020 19:55:38 |
| Data point term sent to Coder                                                                                                                                        | System                               | 28 Oct 2020 19:01:32 |
| User entered 'Kidney Stones'                                                                                                                                         | (b) (4), (b) (6)<br>(b) (4), (b) (6) | 28 Oct 2020 19:00:42 |



US3762161

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 26 Nov 2020 11:14:36**

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

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| User entered 'UN UNK 1995' | (b) (4), (b) (6) | 28 Oct 2020 19:00:42 |
|                            |                  |                      |

US3762161

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 26 Nov 2020 11:14:36**

[Start date completely unknown](#)

| Audit            | User             | Time (GMT)           |
|------------------|------------------|----------------------|
| User entered '0' | (b) (4), (b) (6) | 28 Oct 2020 19:00:42 |
|                  |                  |                      |

US3762161

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 26 Nov 2020 11:14:36**

[Condition ongoing at study entry](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| User entered 'No (N)' | (b) (4), (b) (6) | 28 Oct 2020 19:00:42 |
|                       |                  |                      |

US3762161

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 26 Nov 2020 11:14:36**

If No, please specify the stop date (dd MMM yyyy)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| User entered 'UN UNK 2017' | (b) (4), (b) (6) | 28 Oct 2020 19:00:42 |
|                            |                  |                      |

US3762161

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 26 Nov 2020 11:14:36**

[Stop date completely unknown](#)

| Audit            | User             | Time (GMT)           |
|------------------|------------------|----------------------|
| User entered '0' | (b) (4), (b) (6) | 28 Oct 2020 19:00:42 |
|                  |                  |                      |

**US3762161**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 26 Nov 2020 11:14:36**

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

| Audit                   | User   | Time (GMT)           |
|-------------------------|--------|----------------------|
| User entered 'Jan 1995' | System | 28 Oct 2020 19:00:42 |

US3762161

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 26 Nov 2020 11:14:36**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '1995' | System | 28 Oct 2020 19:00:42 |

**US3762161**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 26 Nov 2020 11:14:36**

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

| Audit                   | User   | Time (GMT)           |
|-------------------------|--------|----------------------|
| User entered 'Jan 2017' | System | 28 Oct 2020 19:00:42 |



US3762161

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 26 Nov 2020 11:14:36**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '2017' | System | 28 Oct 2020 19:00:42 |

US3762161

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:14:36

[Condition](#)

| Audit                                                                                                                                                                                                                     | User                                 | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------|----------------------|
| User coded data point as SOC: Surgical and medical procedures, HLGT: Male genital tract therapeutic procedures, HLT: Male genital tract therapeutic procedures NEC, PT: Vasectomy, LLT: Vasectomy - version MedDRA\\23.0. | Coder Import (b) (4)<br>(b) (4)      | 29 Oct 2020 19:55:40 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.                                                                                                                              | Coder Import (b) (4)<br>(b) (4)      | 29 Oct 2020 19:55:40 |
| Data point term sent to Coder                                                                                                                                                                                             | System                               | 28 Oct 2020 19:02:36 |
| User entered 'Vasectomy'                                                                                                                                                                                                  | (b) (4), (b) (6)<br>(b) (4), (b) (6) | 28 Oct 2020 19:02:14 |

US3762161

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 26 Nov 2020 11:14:36**

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

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| User entered 'UN UNK 1981' | (b) (4), (b) (6) | 28 Oct 2020 19:02:14 |
|                            |                  |                      |

US3762161

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 26 Nov 2020 11:14:36**

[Start date completely unknown](#)

| Audit            | User             | Time (GMT)           |
|------------------|------------------|----------------------|
| User entered '0' | (b) (4), (b) (6) | 28 Oct 2020 19:02:14 |
|                  |                  |                      |

US3762161

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 26 Nov 2020 11:14:36**

[Condition ongoing at study entry](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| User entered 'No (N)' | (b) (4), (b) (6) | 28 Oct 2020 19:02:14 |
|                       |                  |                      |

US3762161

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 26 Nov 2020 11:14:36**

If No, please specify the stop date (dd MMM yyyy)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| User entered 'UN UNK 1981' | (b) (4), (b) (6) | 28 Oct 2020 19:02:14 |
|                            |                  |                      |

US3762161

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 26 Nov 2020 11:14:36**

[Stop date completely unknown](#)

| Audit            | User             | Time (GMT)           |
|------------------|------------------|----------------------|
| User entered '0' | (b) (4), (b) (6) | 28 Oct 2020 19:02:14 |
|                  |                  |                      |

**US3762161**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 26 Nov 2020 11:14:36**

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

| Audit                   | User   | Time (GMT)           |
|-------------------------|--------|----------------------|
| User entered 'Jan 1981' | System | 28 Oct 2020 19:02:14 |



US3762161

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 26 Nov 2020 11:14:36**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '1981' | System | 28 Oct 2020 19:02:14 |

US3762161

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 26 Nov 2020 11:14:36**

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

| Audit                   | User   | Time (GMT)           |
|-------------------------|--------|----------------------|
| User entered 'Jan 1981' | System | 28 Oct 2020 19:02:14 |

US3762161

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 26 Nov 2020 11:14:36**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '1981' | System | 28 Oct 2020 19:02:14 |

US3762161

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:14:36

[Were vital signs assessed?](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 28 Oct 2020 18:48:42 |
|                        |                  |                      |

US3762161

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:14:36

Date of assessment (*dd MMM yyyy*)

| Audit                     | User             | Time (GMT)           |
|---------------------------|------------------|----------------------|
| User entered '2 Sep 2020' | (b) (4), (b) (6) | 28 Oct 2020 18:48:42 |
|                           |                  |                      |

US3762161

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:14:36

Time of assessment (00:00-23:59)

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| User entered '14:22' | (b) (4), (b) (6) | 28 Oct 2020 18:48:42 |
|                      |                  |                      |

US3762161

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:14:36

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

| Audit                           | User   | Time (GMT)           |
|---------------------------------|--------|----------------------|
| User entered '2 Sep 2020 14:22' | System | 28 Oct 2020 18:48:42 |

US3762161

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:14:36

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

| Audit                     | User             | Time (GMT)           |
|---------------------------|------------------|----------------------|
| User entered '68' in      | (b) (4), (b) (6) | 28 Oct 2020 18:48:42 |
| DataPoint set to visible. | System           | 02 Sep 2020 19:21:55 |



US3762161

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:14:36

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

| Audit                     | User             | Time (GMT)           |
|---------------------------|------------------|----------------------|
| User entered '205' lb     | (b) (4), (b) (6) | 28 Oct 2020 18:48:42 |
| DataPoint set to visible. | System           | 02 Sep 2020 19:21:55 |

US3762161

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:14:36

BMI (xxx.x)

| Audit                     | User   | Time (GMT)           |
|---------------------------|--------|----------------------|
| User entered '31.23532'   | System | 28 Oct 2020 18:48:42 |
| DataPoint set to visible. | System | 02 Sep 2020 19:21:55 |

**US3762161**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 11:14:36**

[BMI units](#)

| Audit                     | User   | Time (GMT)           |
|---------------------------|--------|----------------------|
| User entered 'kg/m2'      | System | 28 Oct 2020 18:48:42 |
| DataPoint set to visible. | System | 02 Sep 2020 19:21:55 |

US3762161

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:14:36

Temperature (xxx.x)

| Audit                                    | User             | Time (GMT)           |
|------------------------------------------|------------------|----------------------|
| User entered missing code ND - Not Done. | (b) (4), (b) (6) | 28 Oct 2020 18:48:42 |
|                                          |                  |                      |

US3762161

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:14:36

[Route of measurement](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 28 Oct 2020 18:48:42 |
|                     |                  |                      |

US3762161

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:14:36

[If Other, specify](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 28 Oct 2020 18:48:42 |
|                     |                  |                      |

US3762161

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:14:36

[Pulse \(xxx\)](#)

| Audit                                    | User             | Time (GMT)           |
|------------------------------------------|------------------|----------------------|
| User entered missing code ND - Not Done. | (b) (4), (b) (6) | 28 Oct 2020 18:48:42 |
|                                          |                  |                      |

**US3762161**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 11:14:36**

[Pulse units](#)

| Audit              | User   | Time (GMT)           |
|--------------------|--------|----------------------|
| User entered 'bpm' | System | 28 Oct 2020 18:48:42 |



US3762161

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:14:36

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

| Audit                                    | User             | Time (GMT)           |
|------------------------------------------|------------------|----------------------|
| User entered missing code ND - Not Done. | (b) (4), (b) (6) | 28 Oct 2020 18:48:42 |
|                                          |                  |                      |

US3762161

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 11:14:36**

[Respiratory Rate units](#)

| Audit                      | User   | Time (GMT)           |
|----------------------------|--------|----------------------|
| User entered 'breaths/min' | System | 28 Oct 2020 18:48:42 |

US3762161

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:14:36

Systolic Blood Pressure (xxx)

| Audit                                    | User             | Time (GMT)           |
|------------------------------------------|------------------|----------------------|
| User entered missing code ND - Not Done. | (b) (4), (b) (6) | 28 Oct 2020 18:48:42 |
|                                          |                  |                      |

US3762161

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 11:14:36**

[Systolic Blood Pressure units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 28 Oct 2020 18:48:42 |

US3762161

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:14:36

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

| Audit                                    | User             | Time (GMT)           |
|------------------------------------------|------------------|----------------------|
| User entered missing code ND - Not Done. | (b) (4), (b) (6) | 28 Oct 2020 18:48:42 |
|                                          |                  |                      |

US3762161

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 11:14:36**

[Diastolic Blood Pressure units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 28 Oct 2020 18:48:42 |

US3762161

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 11:14:36

[Was the physical examination performed?](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 28 Oct 2020 18:49:10 |
|                        |                  |                      |

US3762161

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 11:14:36

Date of examination (*dd MMM yyyy*)

| Audit                     | User             | Time (GMT)           |
|---------------------------|------------------|----------------------|
| User entered '2 Sep 2020' | (b) (4), (b) (6) | 28 Oct 2020 18:49:10 |
|                           |                  |                      |



US3762161

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:14:36

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

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| User entered 'No (N)' | (b) (4), (b) (6) | 28 Oct 2020 18:49:49 |
|                       |                  |                      |

US3762161

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:14:36

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

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| User entered 'No (N)' | (b) (4), (b) (6) | 28 Oct 2020 18:49:49 |
|                       |                  |                      |

US3762161

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:14:36

**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 entered 'No (N)' | (b) (4), (b) (6) | 28 Oct 2020 18:49:49 |
|                       |                  |                      |

US3762161

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:14:36

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

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| User entered 'No (N)' | (b) (4), (b) (6) | 28 Oct 2020 18:49:49 |
|                       |                  |                      |

US3762161

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:14:36

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

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| User entered 'No (N)' | (b) (4), (b) (6) | 28 Oct 2020 18:49:49 |
|                       |                  |                      |

US3762161

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:14:36

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

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| User entered 'No (N)' | (b) (4), (b) (6) | 28 Oct 2020 18:49:49 |
|                       |                  |                      |

US3762161

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:14:36

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

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| User entered 'No (N)' | (b) (4), (b) (6) | 28 Oct 2020 18:49:49 |
|                       |                  |                      |

US3762161

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:14:36

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

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| User entered 'No (N)' | (b) (4), (b) (6) | 28 Oct 2020 18:49:49 |
|                       |                  |                      |



US3762161

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:14:36

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

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| User entered 'No (N)' | (b) (4), (b) (6) | 28 Oct 2020 18:49:49 |
|                       |                  |                      |

US3762161

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:14:36

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

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| User entered 'No (N)' | (b) (4), (b) (6) | 28 Oct 2020 18:49:49 |
|                       |                  |                      |

US3762161

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:14:36

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

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| User entered 'No (N)' | (b) (4), (b) (6) | 28 Oct 2020 18:49:49 |
|                       |                  |                      |

US3762161

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:14:36

[Other](#)

| Audit                                                                                  | User             | Time (GMT)           |
|----------------------------------------------------------------------------------------|------------------|----------------------|
| User closed query 'Data is required. Please complete.' (Site from System).             | System           | 28 Oct 2020 18:49:55 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System           | 28 Oct 2020 18:49:55 |
| User entered 'No (N)' reason for change: Data Entry Error                              | (b) (4), (b) (6) | 28 Oct 2020 18:49:55 |
| User opened query 'Data is required. Please complete.' (Site from System).             | System           | 28 Oct 2020 18:49:49 |
| User entered empty.                                                                    | (b) (4), (b) (6) | 28 Oct 2020 18:49:49 |

US3762161

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:14:36

[Specify](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 28 Oct 2020 18:49:49 |
|                     |                  |                      |

US3762161

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:14:36

No Risk Identified

| Audit            | User             | Time (GMT)           |
|------------------|------------------|----------------------|
| User entered '1' | (b) (4), (b) (6) | 28 Oct 2020 18:49:49 |
|                  |                  |                      |

US3762161

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:14:36

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

| Audit            | User             | Time (GMT)           |
|------------------|------------------|----------------------|
| User entered '0' | (b) (4), (b) (6) | 28 Oct 2020 18:49:49 |
|                  |                  |                      |

US3762161

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:14:36

**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' | (b) (4), (b) (6) | 28 Oct 2020 18:49:49 |
|                  |                  |                      |



US3762161

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:14:36

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

| Audit            | User             | Time (GMT)           |
|------------------|------------------|----------------------|
| User entered '0' | (b) (4), (b) (6) | 28 Oct 2020 18:49:49 |
|                  |                  |                      |

US3762161

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:14:36

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

| Audit            | User             | Time (GMT)           |
|------------------|------------------|----------------------|
| User entered '0' | (b) (4), (b) (6) | 28 Oct 2020 18:49:49 |
|                  |                  |                      |

US3762161

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:14:36

[Resides in a single family home](#) (i.e., detached housing)

| Audit            | User             | Time (GMT)           |
|------------------|------------------|----------------------|
| User entered '0' | (b) (4), (b) (6) | 28 Oct 2020 18:49:49 |
|                  |                  |                      |

US3762161

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:14:36

[Other](#)

| Audit            | User             | Time (GMT)           |
|------------------|------------------|----------------------|
| User entered '0' | (b) (4), (b) (6) | 28 Oct 2020 18:49:49 |
|                  |                  |                      |

US3762161

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:14:36

[Specify](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 28 Oct 2020 18:49:49 |
|                     |                  |                      |

US3762161

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:14:36

[Was this visit performed?](#)

| Audit                  | User                     | Time (GMT)           |
|------------------------|--------------------------|----------------------|
| User entered 'Yes (Y)' | Samantha Wheeler (b) (4) | 02 Sep 2020 19:29:14 |
|                        | (b) (4)                  |                      |

US3762161

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:14:36

Visit date (dd MMM yyyy)

| Audit                                                                                                                                                                                                                                                                                                                                                         | User                          | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------|----------------------|
| User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 2SEP2020 is reported under Visit 1 Day 1visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).                 | (b) (4), (b) (6)              | 04 Nov 2020 10:33:38 |
| User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated 02SEP2020 is reported under Visit 1 Day 1 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).                                           | (b) (4), (b) (6)              | 04 Nov 2020 07:07:42 |
| Query 'Per GCL Lab Reconciliation: Swab: Sample dated 02SEP2020 is reported under Visit 1 Day 1 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' answered with 'updated edc' (Site from DM).                           | Kaitlyn Van Leuvan<br>(b) (4) | 03 Nov 2020 20:32:49 |
| Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 2SEP2020 is reported under Visit 1 Day 1visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' answered with 'updated edc' (Site from DM). | Kaitlyn Van Leuvan<br>(b) (4) | 03 Nov 2020 20:32:43 |
| User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 02SEP2020 is reported under Visit 1 Day 1 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).                                           | (b) (4), (b) (6)              | 22 Oct 2020 08:53:15 |





US3762161

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:14:36

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

| Audit                          | User                     | Time (GMT)           |
|--------------------------------|--------------------------|----------------------|
| User entered 'Clinic (Clinic)' | Samantha Wheeler (b) (4) | 02 Sep 2020 19:29:14 |
|                                | (b) (4)                  |                      |

**US3762161**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 26 Nov 2020 11:14:36**

[Folder OID](#)

| Audit                 | User   | Time (GMT)           |
|-----------------------|--------|----------------------|
| User entered 'VISIT1' | System | 02 Sep 2020 19:29:14 |

US3762161

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:14:36

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

| Audit                      | User                                            | Time (GMT)           |
|----------------------------|-------------------------------------------------|----------------------|
| User entered '02 SEP 2020' | RWS_ENDPOINT<br>ENDPOINT (b) (4)<br><div></div> | 02 Sep 2020 19:05:16 |

US3762161

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:14:36

[What was the participant's randomization number?](#)

| Audit                 | User                                            | Time (GMT)           |
|-----------------------|-------------------------------------------------|----------------------|
| User entered '189561' | RWS_ENDPOINT<br>ENDPOINT (b) (4)<br><div></div> | 02 Sep 2020 19:05:16 |

US3762161

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:14:36

[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> | 02 Sep 2020 19:05:16 |

US3762161

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:14:36

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

| Audit                                                                                                                                                                      | User                     | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|----------------------|
| User closed query 'Per CDM: Please complete this section of the form (a required response (Yes or No) is needed for each), otherwise explain.' (Site from DM).             | (b) (4), (b) (6)         | 21 Sep 2020 11:10:58 |
| Query 'Per CDM: Please complete this section of the form (a required response (Yes or No) is needed for each), otherwise explain.' answered with 'Updated' (Site from DM). | Samantha Wheeler (b) (4) | 21 Sep 2020 00:52:22 |
| User entered 'No (N)'                                                                                                                                                      | Samantha Wheeler (b) (4) | 21 Sep 2020 00:52:13 |
| User opened query 'Per CDM: Please complete this section of the form (a required response (Yes or No) is needed for each), otherwise explain.' (Site from DM).             | (b) (4), (b) (6)         | 04 Sep 2020 13:03:18 |

US3762161

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:14:36

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

| Audit                 | User                                | Time (GMT)           |
|-----------------------|-------------------------------------|----------------------|
| User entered 'No (N)' | Samantha Wheeler (b) (4)<br>(b) (4) | 21 Sep 2020 00:52:13 |

US3762161

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:14:36

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

| Audit                 | User                     | Time (GMT)           |
|-----------------------|--------------------------|----------------------|
| User entered 'No (N)' | Samantha Wheeler (b) (4) | 21 Sep 2020 00:52:13 |
|                       | (b) (4)                  |                      |



US3762161

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:14:36

Diabetes (Type I, Type 2, or gestational)

| Audit                 | User                                | Time (GMT)           |
|-----------------------|-------------------------------------|----------------------|
| User entered 'No (N)' | Samantha Wheeler (b) (4)<br>(b) (4) | 21 Sep 2020 00:52:13 |

US3762161

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:14:36

[Liver Disease](#)

| Audit                 | User                                | Time (GMT)           |
|-----------------------|-------------------------------------|----------------------|
| User entered 'No (N)' | Samantha Wheeler (b) (4)<br>(b) (4) | 21 Sep 2020 00:52:13 |

US3762161

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:14:36

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

| Audit                                        | User                     | Time (GMT)           |
|----------------------------------------------|--------------------------|----------------------|
| User entered 'No (N)'                        | Samantha Wheeler (b) (4) | 21 Sep 2020 00:52:13 |
|                                              | (b) (4)                  |                      |
| Amendment Manager: DataPoint set to visible. | System                   | 19 Sep 2020 04:57:49 |
| Amendment Manager inserted this DataPoint.   | System                   | 19 Sep 2020 04:57:49 |

US3762161

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:14:36

Height

| Audit                                    | User                          | Time (GMT)           |
|------------------------------------------|-------------------------------|----------------------|
| User entered missing code ND - Not Done. | Kaitlyn Van Leuvan<br>(b) (4) | 03 Nov 2020 17:50:25 |

US3762161

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:14:36

Weight

| Audit                                    | User                          | Time (GMT)           |
|------------------------------------------|-------------------------------|----------------------|
| User entered missing code ND - Not Done. | Kaitlyn Van Leuvan<br>(b) (4) | 03 Nov 2020 17:50:25 |

US3762161

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:14:36

Height

| Audit                                    | User                          | Time (GMT)           |
|------------------------------------------|-------------------------------|----------------------|
| User entered missing code ND - Not Done. | Kaitlyn Van Leuvan<br>(b) (4) | 03 Nov 2020 17:50:25 |

US3762161

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:14:36

Weight

| Audit                                    | User                          | Time (GMT)           |
|------------------------------------------|-------------------------------|----------------------|
| User entered missing code ND - Not Done. | Kaitlyn Van Leuvan<br>(b) (4) | 03 Nov 2020 17:50:25 |

US3762161

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:14:36

[Timepoint](#)

| Audit                                            | User                          | Time (GMT)           |
|--------------------------------------------------|-------------------------------|----------------------|
| User accepted default value 'Pre-Dose (PREDOSE)' | Kaitlyn Van Leuvan<br>(b) (4) | 03 Nov 2020 17:50:25 |



US3762161

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:14:36

[Were vital signs assessed?](#)

| Audit                  | User                          | Time (GMT)           |
|------------------------|-------------------------------|----------------------|
| User entered 'Yes (Y)' | Kaitlyn Van Leuvan<br>(b) (4) | 03 Nov 2020 17:50:25 |

US3762161

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:14:36

Date of assessment (*dd MMM yyyy*)

| Audit                      | User                          | Time (GMT)           |
|----------------------------|-------------------------------|----------------------|
| User entered '02 Sep 2020' | Kaitlyn Van Leuvan<br>(b) (4) | 03 Nov 2020 17:50:25 |

US3762161

**Folder: Visit 1 Day 1**

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

**Generated On: 26 Nov 2020 11:14:36**

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

| Audit                | User                          | Time (GMT)           |
|----------------------|-------------------------------|----------------------|
| User entered '14:22' | Kaitlyn Van Leuvan<br>(b) (4) | 03 Nov 2020 17:50:25 |

US3762161

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:14:36

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

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '02 Sep 2020 14:22' | System | 03 Nov 2020 17:50:25 |

US3762161

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:14:36

Temperature (xxx.x)

| Audit                 | User                          | Time (GMT)           |
|-----------------------|-------------------------------|----------------------|
| User entered '97.0' F | Kaitlyn Van Leuvan<br>(b) (4) | 03 Nov 2020 17:50:25 |

US3762161

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:14:36

[Route of measurement](#)

| Audit                      | User                          | Time (GMT)           |
|----------------------------|-------------------------------|----------------------|
| User entered 'Oral (Oral)' | Kaitlyn Van Leuvan<br>(b) (4) | 03 Nov 2020 17:50:25 |

US3762161

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:14:36

[If Other, specify](#)

| Audit               | User                          | Time (GMT)           |
|---------------------|-------------------------------|----------------------|
| User entered empty. | Kaitlyn Van Leuvan<br>(b) (4) | 03 Nov 2020 17:50:25 |

US3762161

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:14:36

Pulse (xxx)

| Audit             | User                          | Time (GMT)           |
|-------------------|-------------------------------|----------------------|
| User entered '77' | Kaitlyn Van Leuvan<br>(b) (4) | 03 Nov 2020 17:50:25 |



**US3762161**

**Folder: Visit 1 Day 1**

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

**Generated On: 26 Nov 2020 11:14:36**

[Pulse units](#)

| Audit              | User   | Time (GMT)           |
|--------------------|--------|----------------------|
| User entered 'bpm' | System | 03 Nov 2020 17:50:25 |

US3762161

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:14:36

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

| Audit             | User                          | Time (GMT)           |
|-------------------|-------------------------------|----------------------|
| User entered '16' | Kaitlyn Van Leuvan<br>(b) (4) | 03 Nov 2020 17:50:25 |

US3762161

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:14:36

[Respiratory Rate units](#)

| Audit                      | User   | Time (GMT)           |
|----------------------------|--------|----------------------|
| User entered 'breaths/min' | System | 03 Nov 2020 17:50:25 |

US3762161

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:14:36

Systolic Blood Pressure (xxx)

| Audit              | User                          | Time (GMT)           |
|--------------------|-------------------------------|----------------------|
| User entered '135' | Kaitlyn Van Leuvan<br>(b) (4) | 03 Nov 2020 17:50:25 |

US3762161

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:14:36

[Systolic Blood Pressure units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 03 Nov 2020 17:50:25 |

US3762161

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:14:36

Diastolic Blood Pressure (xxx)

| Audit             | User                          | Time (GMT)           |
|-------------------|-------------------------------|----------------------|
| User entered '79' | Kaitlyn Van Leuvan<br>(b) (4) | 03 Nov 2020 17:50:25 |

US3762161

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:14:36

[Diastolic Blood Pressure units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 03 Nov 2020 17:50:25 |

US3762161

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:14:36

Height

| Audit                                    | User                          | Time (GMT)           |
|------------------------------------------|-------------------------------|----------------------|
| User entered missing code ND - Not Done. | Kaitlyn Van Leuvan<br>(b) (4) | 03 Nov 2020 17:50:25 |



US3762161

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:14:36

Weight

| Audit                                    | User                          | Time (GMT)           |
|------------------------------------------|-------------------------------|----------------------|
| User entered missing code ND - Not Done. | Kaitlyn Van Leuvan<br>(b) (4) | 03 Nov 2020 17:50:25 |

US3762161

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:14:36

[Timepoint](#)

| Audit                                              | User                          | Time (GMT)           |
|----------------------------------------------------|-------------------------------|----------------------|
| User accepted default value 'Post-Dose (POSTDOSE)' | Kaitlyn Van Leuvan<br>(b) (4) | 03 Nov 2020 17:50:25 |

US3762161

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:14:36

[Were vital signs assessed?](#)

| Audit                  | User                          | Time (GMT)           |
|------------------------|-------------------------------|----------------------|
| User entered 'Yes (Y)' | Kaitlyn Van Leuvan<br>(b) (4) | 03 Nov 2020 17:50:25 |

US3762161

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:14:36

Date of assessment (*dd MMM yyyy*)

| Audit                      | User                          | Time (GMT)           |
|----------------------------|-------------------------------|----------------------|
| User entered '02 Sep 2020' | Kaitlyn Van Leuvan<br>(b) (4) | 03 Nov 2020 17:50:25 |

US3762161

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:14:36

Time of assessment (00:00-23:59)

| Audit                | User                          | Time (GMT)           |
|----------------------|-------------------------------|----------------------|
| User entered '15:50' | Kaitlyn Van Leuvan<br>(b) (4) | 03 Nov 2020 17:50:25 |

US3762161

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:14:36

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

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '02 Sep 2020 15:50' | System | 03 Nov 2020 17:50:25 |

US3762161

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:14:36

Temperature (xxx.x)

| Audit                 | User                          | Time (GMT)           |
|-----------------------|-------------------------------|----------------------|
| User entered '97.4' F | Kaitlyn Van Leuvan<br>(b) (4) | 03 Nov 2020 17:50:25 |

US3762161

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 11:14:36**

[Route of measurement](#)

| Audit                      | User                          | Time (GMT)           |
|----------------------------|-------------------------------|----------------------|
| User entered 'Oral (Oral)' | Kaitlyn Van Leuvan<br>(b) (4) | 03 Nov 2020 17:50:25 |



US3762161

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:14:36

[If Other, specify](#)

| Audit               | User                          | Time (GMT)           |
|---------------------|-------------------------------|----------------------|
| User entered empty. | Kaitlyn Van Leuvan<br>(b) (4) | 03 Nov 2020 17:50:25 |

US3762161

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:14:36

Pulse (xxx)

| Audit             | User                          | Time (GMT)           |
|-------------------|-------------------------------|----------------------|
| User entered '71' | Kaitlyn Van Leuvan<br>(b) (4) | 03 Nov 2020 17:50:25 |

US3762161

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:14:36

[Pulse units](#)

| Audit              | User   | Time (GMT)           |
|--------------------|--------|----------------------|
| User entered 'bpm' | System | 03 Nov 2020 17:50:25 |

US3762161

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:14:36

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

| Audit             | User                          | Time (GMT)           |
|-------------------|-------------------------------|----------------------|
| User entered '17' | Kaitlyn Van Leuvan<br>(b) (4) | 03 Nov 2020 17:50:25 |

US3762161

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:14:36

[Respiratory Rate units](#)

| Audit                      | User   | Time (GMT)           |
|----------------------------|--------|----------------------|
| User entered 'breaths/min' | System | 03 Nov 2020 17:50:25 |

US3762161

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:14:36

Systolic Blood Pressure (xxx)

| Audit              | User                          | Time (GMT)           |
|--------------------|-------------------------------|----------------------|
| User entered '138' | Kaitlyn Van Leuvan<br>(b) (4) | 03 Nov 2020 17:50:25 |

US3762161

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:14:36

[Systolic Blood Pressure units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 03 Nov 2020 17:50:25 |

US3762161

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:14:36

Diastolic Blood Pressure (xxx)

| Audit             | User                          | Time (GMT)           |
|-------------------|-------------------------------|----------------------|
| User entered '76' | Kaitlyn Van Leuvan<br>(b) (4) | 03 Nov 2020 17:50:25 |



US3762161

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:14:36

[Diastolic Blood Pressure units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 03 Nov 2020 17:50:25 |

US3762161

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 11:14:36

Was the physical examination performed?

| Audit                  | User                          | Time (GMT)           |
|------------------------|-------------------------------|----------------------|
| User entered 'Yes (Y)' | Kaitlyn Van Leuvan<br>(b) (4) | 03 Nov 2020 17:50:37 |

US3762161

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 11:14:36

Date of examination (*dd MMM yyyy*)

| Audit                      | User                          | Time (GMT)           |
|----------------------------|-------------------------------|----------------------|
| User entered '02 Sep 2020' | Kaitlyn Van Leuvan<br>(b) (4) | 03 Nov 2020 17:50:37 |

US3762161

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:14:36

[Was study treatment given?](#)

| Audit                  | User                     | Time (GMT)           |
|------------------------|--------------------------|----------------------|
| User entered 'Yes (Y)' | Samantha Wheeler (b) (4) | 02 Sep 2020 19:29:34 |
|                        | (b) (4)                  |                      |

US3762161

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:14:36

If No, reason not given

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| User entered empty. | Samantha Wheeler (b) (4) | 02 Sep 2020 19:29:34 |
|                     | (b) (4)                  |                      |

US3762161

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:14:36

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

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| User entered empty. | Samantha Wheeler (b) (4) | 02 Sep 2020 19:29:34 |
|                     | (b) (4)                  |                      |

US3762161

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:14:36

[What was the study treatment?](#)

| Audit                               | User   | Time (GMT)           |
|-------------------------------------|--------|----------------------|
| User entered 'MRNA-1273 OR PLACEBO' | System | 02 Sep 2020 19:29:34 |

US3762161

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:14:36

What was the treatment date? (dd MMM yyyy)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| User entered '02 Sep 2020' | Samantha Wheeler (b) (4) | 02 Sep 2020 19:29:34 |
|                            | (b) (4)                  |                      |



US3762161

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:14:36

[What was the treatment time? \(00:00-23:59\)](#)

| Audit                | User                     | Time (GMT)           |
|----------------------|--------------------------|----------------------|
| User entered '15:12' | Samantha Wheeler (b) (4) | 02 Sep 2020 19:29:34 |
|                      | (b) (4)                  |                      |

US3762161

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:14:36

[Treatment Date and Time \(derived\)](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '02 Sep 2020 15:12' | System | 02 Sep 2020 19:29:34 |

US3762161

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:14:36

[Which arm was used to give treatment?](#)

| Audit                              | User                     | Time (GMT)           |
|------------------------------------|--------------------------|----------------------|
| User entered 'Left Arm (LEFT ARM)' | Samantha Wheeler (b) (4) | 02 Sep 2020 19:29:34 |
|                                    | (b) (4)                  |                      |

US3762161

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:14:36

[What was the frequency of the study treatment dosing?](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'ONCE' | System | 02 Sep 2020 19:29:34 |

US3762161

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:14:36

[What was the route of administration for the study treatment?](#)

| Audit                        | User   | Time (GMT)           |
|------------------------------|--------|----------------------|
| User entered 'INTRAMUSCULAR' | System | 02 Sep 2020 19:29:34 |

US3762161

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:14:36

[Was the sample collected?](#)

| Audit                  | User                          | Time (GMT)           |
|------------------------|-------------------------------|----------------------|
| User entered 'Yes (Y)' | Kaitlyn Van Leuvan<br>(b) (4) | 03 Nov 2020 17:51:01 |

US3762161

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:14:36

Collection date (*dd MMM yyyy*)

| Audit                      | User                          | Time (GMT)           |
|----------------------------|-------------------------------|----------------------|
| User entered '02 Sep 2020' | Kaitlyn Van Leuvan<br>(b) (4) | 03 Nov 2020 17:51:01 |

US3762161

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:14:36

Collection time (00:00-23:59)

| Audit                | User                          | Time (GMT)           |
|----------------------|-------------------------------|----------------------|
| User entered '14:59' | Kaitlyn Van Leuvan<br>(b) (4) | 03 Nov 2020 17:51:01 |



US3762161

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:14:36

[Collection date and time \(derived\)](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '02 Sep 2020 14:59' | System | 03 Nov 2020 17:51:01 |

US3762161

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 11:14:36

Collection date (*dd MMM yyyy*)

| Audit                      | User                          | Time (GMT)           |
|----------------------------|-------------------------------|----------------------|
| User entered '02 Sep 2020' | Kaitlyn Van Leuvan<br>(b) (4) | 03 Nov 2020 17:51:15 |

US3762161

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:14:36

[Lab Test](#)

| Audit                                                        | User                          | Time (GMT)           |
|--------------------------------------------------------------|-------------------------------|----------------------|
| User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)' | Kaitlyn Van Leuvan<br>(b) (4) | 03 Nov 2020 17:51:15 |

US3762161

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:14:36

[Was the sample collected?](#)

| Audit                  | User                          | Time (GMT)           |
|------------------------|-------------------------------|----------------------|
| User entered 'Yes (Y)' | Kaitlyn Van Leuvan<br>(b) (4) | 03 Nov 2020 17:51:15 |

US3762161

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:14:36

Collection time (00:00 - 23:59)

| Audit                | User                          | Time (GMT)           |
|----------------------|-------------------------------|----------------------|
| User entered '14:55' | Kaitlyn Van Leuvan<br>(b) (4) | 03 Nov 2020 17:51:15 |

**US3762161**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 26 Nov 2020 11:14:36**

[Collection date and time \(derived\)](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '02 Sep 2020 14:55' | System | 03 Nov 2020 17:51:15 |

US3762161

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:14:36

[Lab Test](#)

| Audit                                                        | User                          | Time (GMT)           |
|--------------------------------------------------------------|-------------------------------|----------------------|
| User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)' | Kaitlyn Van Leuvan<br>(b) (4) | 03 Nov 2020 17:51:15 |

US3762161

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:14:36

[Was the sample collected?](#)

| Audit                 | User                          | Time (GMT)           |
|-----------------------|-------------------------------|----------------------|
| User entered 'No (N)' | Kaitlyn Van Leuvan<br>(b) (4) | 03 Nov 2020 17:51:15 |



US3762161

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:14:36

Collection time (00:00 - 23:59)

| Audit               | User                          | Time (GMT)           |
|---------------------|-------------------------------|----------------------|
| User entered empty. | Kaitlyn Van Leuvan<br>(b) (4) | 03 Nov 2020 17:51:15 |

**US3762161**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 26 Nov 2020 11:14:36**

[Collection date and time \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 03 Nov 2020 17:51:15 |

US3762161

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 11:14:36

[Is the participant continuing to the next visit?](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 30 Sep 2020 20:23:01 |
|                        |                  |                      |

**US3762161**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 26 Nov 2020 11:14:36**

[Continuing Flag](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 30 Sep 2020 20:23:01 |

US3762161

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 26 Nov 2020 11:14:36

**TIMEPOINT**

| Audit                                                                | User   | Time (GMT)           |
|----------------------------------------------------------------------|--------|----------------------|
| Data entry locked.                                                   | System | 02 Sep 2020 19:29:34 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 02 Sep 2020 19:29:34 |

US3762161

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 26 Nov 2020 11:14:36

Was **TEMPERATURE** taken?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-02T15:55:12', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: 'f8c94309-2985-4e42-9e51-4456587c61eb' | System | 02 Sep 2020 19:55:55 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                                         | System | 02 Sep 2020 19:55:55 |

US3762161

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 26 Nov 2020 11:14:36

Please record your **TEMPERATURE** in °F

| Audit                                                                                                                                                                                                                                                                              | User   | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-02T15:55:25', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: 'f8c94309-2985-4e42-9e51-4456587c61eb' User entered '97.4' | System | 02 Sep 2020 19:55:55 |

US3762161

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 26 Nov 2020 11:14:36

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

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-02T15:55:30', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: 'f8c94309-2985-4e42-9e51-4456587c61eb' | System | 02 Sep 2020 19:55:55 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 02 Sep 2020 19:55:55 |



US3762161

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 26 Nov 2020 11:14:36

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-02T15:55:52', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: 'f8c94309-2985-4e42-9e51-4456587c61eb' | System | 02 Sep 2020 19:55:55 |
| User entered '02 Sep 2020 15:55'                                                                                                                                                                                                                               | System | 02 Sep 2020 19:55:55 |

US3762161

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 26 Nov 2020 11:14:36

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '02 Sep 2020 15:32' | System | 02 Sep 2020 19:29:34 |

US3762161

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 26 Nov 2020 11:14:36**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '02 Sep 2020 18:02' | System | 02 Sep 2020 19:29:34 |

US3762161

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 26 Nov 2020 11:14:36

**TIMEPOINT**

| Audit                                             | User   | Time (GMT)           |
|---------------------------------------------------|--------|----------------------|
| Data entry locked.                                | System | 02 Sep 2020 19:29:34 |
| User entered 'Day 1, after vaccination (at home)' | System | 02 Sep 2020 19:29:34 |

US3762161

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 26 Nov 2020 11:14:36

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '02 Sep 2020 18:57' | System | 02 Sep 2020 19:29:34 |

US3762161

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 26 Nov 2020 11:14:36**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '03 Sep 2020 11:59' | System | 02 Sep 2020 19:29:34 |

US3762161

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 11:14:36

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 02 Sep 2020 19:29:34 |
| User entered 'Day 2' | System | 02 Sep 2020 19:29:34 |

US3762161

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 11:14:36

Was **TEMPERATURE** taken?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-03T14:31:46', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: 'bab6a60e-59c6-43f1-a2d5-fb1d0facb2b0' | System | 11 Sep 2020 02:20:59 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                                         | System | 11 Sep 2020 02:20:59 |



US3762161

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 11:14:36

Please record your **TEMPERATURE** in °F

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-03T14:32:00', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: 'bab6a60e-59c6-43f1-a2d5-fb1d0facb2b0' | System | 11 Sep 2020 02:20:59 |
| User entered '97.7'                                                                                                                                                                                                                                            | System | 11 Sep 2020 02:20:59 |

US3762161

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 11:14:36

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

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-03T14:32:10', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: 'bab6a60e-59c6-43f1-a2d5-fb1d0facb2b0' | System | 11 Sep 2020 02:20:59 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 11 Sep 2020 02:20:59 |

**US3762161**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 26 Nov 2020 11:14:36**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-03T14:32:16', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: 'bab6a60e-59c6-43f1-a2d5-fb1d0facb2b0' | System | 11 Sep 2020 02:20:59 |
| User entered '03 Sep 2020 14:32'                                                                                                                                                                                                                               | System | 11 Sep 2020 02:20:59 |

US3762161

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 11:14:36

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '03 Sep 2020 12:00' | System | 02 Sep 2020 19:29:34 |

US3762161

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 26 Nov 2020 11:14:36**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '04 Sep 2020 11:59' | System | 02 Sep 2020 19:29:34 |

US3762161

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 26 Nov 2020 11:14:36

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 02 Sep 2020 19:29:34 |
| User entered 'Day 3' | System | 02 Sep 2020 19:29:34 |

US3762161

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 26 Nov 2020 11:14:36

Was **TEMPERATURE** taken?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-04T21:07:57', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '8a5f190c-5f79-4caf-ac7a-3bf4373837a7' | System | 11 Sep 2020 02:21:05 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                                         | System | 11 Sep 2020 02:21:05 |

US3762161

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 26 Nov 2020 11:14:36

Please record your **TEMPERATURE** in °F

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-04T21:08:06', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '8a5f190c-5f79-4caf-ac7a-3bf4373837a7' | System | 11 Sep 2020 02:21:05 |
| User entered '97.2'                                                                                                                                                                                                                                            | System | 11 Sep 2020 02:21:05 |



US3762161

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 26 Nov 2020 11:14:36

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

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-04T21:08:12', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '8a5f190c-5f79-4caf-ac7a-3bf4373837a7' | System | 11 Sep 2020 02:21:05 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 11 Sep 2020 02:21:05 |

US3762161

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 26 Nov 2020 11:14:36

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-04T21:08:18', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '8a5f190c-5f79-4caf-ac7a-3bf4373837a7' | System | 11 Sep 2020 02:21:05 |
| User entered '04 Sep 2020 21:08'                                                                                                                                                                                                                               | System | 11 Sep 2020 02:21:05 |

US3762161

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 26 Nov 2020 11:14:36

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '04 Sep 2020 12:00' | System | 02 Sep 2020 19:29:34 |

US3762161

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 26 Nov 2020 11:14:36

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '05 Sep 2020 11:59' | System | 02 Sep 2020 19:29:34 |

US3762161

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 11:14:36

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 02 Sep 2020 19:29:34 |
| User entered 'Day 4' | System | 02 Sep 2020 19:29:34 |

US3762161

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 11:14:36

Was **TEMPERATURE** taken?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-05T21:57:50', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '83f2051d-2f66-4675-8218-5eba0b47ba69' | System | 11 Sep 2020 02:21:06 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                                         | System | 11 Sep 2020 02:21:06 |

US3762161

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 11:14:36

Please record your **TEMPERATURE** in °F

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-05T21:57:58', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '83f2051d-2f66-4675-8218-5eba0b47ba69' | System | 11 Sep 2020 02:21:06 |
| User entered '96.1'                                                                                                                                                                                                                                            | System | 11 Sep 2020 02:21:06 |

US3762161

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 11:14:36

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

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-05T21:58:02', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '83f2051d-2f66-4675-8218-5eba0b47ba69' | System | 11 Sep 2020 02:21:06 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 11 Sep 2020 02:21:06 |



US3762161

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 11:14:36

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-05T21:58:06', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '83f2051d-2f66-4675-8218-5eba0b47ba69' | System | 11 Sep 2020 02:21:06 |
| User entered '05 Sep 2020 21:58'                                                                                                                                                                                                                               | System | 11 Sep 2020 02:21:06 |

US3762161

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 11:14:36

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '05 Sep 2020 12:00' | System | 02 Sep 2020 19:29:34 |

US3762161

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 11:14:36

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '06 Sep 2020 11:59' | System | 02 Sep 2020 19:29:34 |

US3762161

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 26 Nov 2020 11:14:36

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 02 Sep 2020 19:29:34 |
| User entered 'Day 5' | System | 02 Sep 2020 19:29:34 |

US3762161

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 26 Nov 2020 11:14:36

Was **TEMPERATURE** taken?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-06T22:53:29', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '54de4760-c8d1-4567-bc74-864e1fc4ca78' | System | 11 Sep 2020 02:21:08 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                                         | System | 11 Sep 2020 02:21:08 |

US3762161

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 26 Nov 2020 11:14:36

Please record your **TEMPERATURE** in °F

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-06T22:53:36', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '54de4760-c8d1-4567-bc74-864e1fc4ca78' | System | 11 Sep 2020 02:21:08 |
| User entered '96.7'                                                                                                                                                                                                                                            | System | 11 Sep 2020 02:21:08 |

US3762161

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 26 Nov 2020 11:14:36

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

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-06T22:53:40', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '54de4760-c8d1-4567-bc74-864e1fc4ca78' | System | 11 Sep 2020 02:21:08 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 11 Sep 2020 02:21:08 |

US3762161

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 26 Nov 2020 11:14:36

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-06T22:53:43', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '54de4760-c8d1-4567-bc74-864e1fc4ca78' | System | 11 Sep 2020 02:21:08 |
| User entered '06 Sep 2020 22:53'                                                                                                                                                                                                                               | System | 11 Sep 2020 02:21:08 |



US3762161

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 26 Nov 2020 11:14:36

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '06 Sep 2020 12:00' | System | 02 Sep 2020 19:29:34 |

US3762161

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 26 Nov 2020 11:14:36**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '07 Sep 2020 11:59' | System | 02 Sep 2020 19:29:34 |

US3762161

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 26 Nov 2020 11:14:36

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 02 Sep 2020 19:29:34 |
| User entered 'Day 6' | System | 02 Sep 2020 19:29:34 |

US3762161

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 26 Nov 2020 11:14:36

Was **TEMPERATURE** taken?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-07T21:39:49', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '72a89106-807f-478d-b382-aede6c19f728' | System | 11 Sep 2020 02:21:12 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                                         | System | 11 Sep 2020 02:21:12 |

US3762161

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 26 Nov 2020 11:14:36

Please record your **TEMPERATURE** in °F

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-07T21:39:56', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '72a89106-807f-478d-b382-aede6c19f728' | System | 11 Sep 2020 02:21:12 |
| User entered '96.3'                                                                                                                                                                                                                                            | System | 11 Sep 2020 02:21:12 |

US3762161

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 26 Nov 2020 11:14:36

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

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-07T21:40:00', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '72a89106-807f-478d-b382-aede6c19f728' | System | 11 Sep 2020 02:21:12 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 11 Sep 2020 02:21:12 |

**US3762161**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 26 Nov 2020 11:14:36**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-07T21:40:03', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '72a89106-807f-478d-b382-aede6c19f728' | System | 11 Sep 2020 02:21:12 |
| User entered '07 Sep 2020 21:40'                                                                                                                                                                                                                               | System | 11 Sep 2020 02:21:12 |

US3762161

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 26 Nov 2020 11:14:36

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '07 Sep 2020 12:00' | System | 02 Sep 2020 19:29:34 |



US3762161

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 26 Nov 2020 11:14:36

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '08 Sep 2020 11:59' | System | 02 Sep 2020 19:29:34 |

US3762161

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 26 Nov 2020 11:14:36

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 02 Sep 2020 19:29:34 |
| User entered 'Day 7' | System | 02 Sep 2020 19:29:34 |

US3762161

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 26 Nov 2020 11:14:36

Was **TEMPERATURE** taken?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-08T22:46:57', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '5bbea2c1-dfdb-4d27-aa72-6d9e85d1685d' | System | 11 Sep 2020 02:21:13 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                                         | System | 11 Sep 2020 02:21:13 |

US3762161

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 26 Nov 2020 11:14:36

Please record your **TEMPERATURE** in °F

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-08T22:47:03', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '5bbea2c1-dfdb-4d27-aa72-6d9e85d1685d' | System | 11 Sep 2020 02:21:13 |
| User entered '95.1'                                                                                                                                                                                                                                            | System | 11 Sep 2020 02:21:13 |

US3762161

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 26 Nov 2020 11:14:36

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

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-08T22:47:07', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '5bbea2c1-dfdb-4d27-aa72-6d9e85d1685d' | System | 11 Sep 2020 02:21:13 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 11 Sep 2020 02:21:13 |

**US3762161**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 26 Nov 2020 11:14:36**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                                                           | User   | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-08T22:47:09', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '5bbea2c1-dfdb-4d27-aa72-6d9e85d1685d' User entered '08 Sep 2020 22:47' | System | 11 Sep 2020 02:21:13 |
|                                                                                                                                                                                                                                                                                                 | System | 11 Sep 2020 02:21:13 |

US3762161

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 26 Nov 2020 11:14:36**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '08 Sep 2020 12:00' | System | 02 Sep 2020 19:29:34 |

US3762161

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 26 Nov 2020 11:14:36**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '09 Sep 2020 11:59' | System | 02 Sep 2020 19:29:34 |



**US3762161**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 11:14:36**

**TIMEPOINT**

| Audit                                                                | User   | Time (GMT)           |
|----------------------------------------------------------------------|--------|----------------------|
| Data entry locked.                                                   | System | 02 Sep 2020 19:29:34 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 02 Sep 2020 19:29:34 |

US3762161

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 11:14:36

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 (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-02T15:56:08', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '222d59c1-4bf6-4386-a02d-4e5d20438f38' | System | 02 Sep 2020 19:56:40 |
| User entered 'None (1)'                                                                                                                                                                                                                                        | System | 02 Sep 2020 19:56:40 |

US3762161

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 11:14:36

Is there any REDNESS AT INJECTION SITE?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-02T15:56:17', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '222d59c1-4bf6-4386-a02d-4e5d20438f38' | System | 02 Sep 2020 19:56:40 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 02 Sep 2020 19:56:40 |

US3762161

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 11:14:36

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

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-02T15:56:22', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '222d59c1-4bf6-4386-a02d-4e5d20438f38' | System | 02 Sep 2020 19:56:40 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 02 Sep 2020 19:56:40 |

US3762161

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 11:14:36

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 (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-02T15:56:30', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '222d59c1-4bf6-4386-a02d-4e5d20438f38' | System | 02 Sep 2020 19:56:40 |
| User entered 'None (1)'                                                                                                                                                                                                                                        | System | 02 Sep 2020 19:56:40 |

**US3762161**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 11:14:36**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-02T15:56:36', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '222d59c1-4bf6-4386-a02d-4e5d20438f38' | System | 02 Sep 2020 19:56:40 |
| User entered '02 Sep 2020 15:56'                                                                                                                                                                                                                               | System | 02 Sep 2020 19:56:40 |

US3762161

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 11:14:36**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '02 Sep 2020 15:32' | System | 02 Sep 2020 19:29:34 |

US3762161

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 11:14:36**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '02 Sep 2020 18:02' | System | 02 Sep 2020 19:29:34 |



US3762161

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 26 Nov 2020 11:14:36

**TIMEPOINT**

| Audit                                             | User   | Time (GMT)           |
|---------------------------------------------------|--------|----------------------|
| Data entry locked.                                | System | 02 Sep 2020 19:29:34 |
| User entered 'Day 1, after vaccination (at home)' | System | 02 Sep 2020 19:29:34 |

US3762161

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 11:14:36**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '02 Sep 2020 18:57' | System | 02 Sep 2020 19:29:34 |

US3762161

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 11:14:36**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '03 Sep 2020 11:59' | System | 02 Sep 2020 19:29:34 |

US3762161

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 26 Nov 2020 11:14:36

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 02 Sep 2020 19:29:34 |
| User entered 'Day 2' | System | 02 Sep 2020 19:29:34 |

US3762161

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 26 Nov 2020 11:14:36

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 (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-03T14:32:42', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '9d08d977-c8f8-4836-b1aa-3a896d6a1583' | System | 11 Sep 2020 02:21:00 |
| User entered 'None (1)'                                                                                                                                                                                                                                        | System | 11 Sep 2020 02:21:00 |

US3762161

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 26 Nov 2020 11:14:36

Is there any REDNESS AT INJECTION SITE?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-03T14:32:47', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '9d08d977-c8f8-4836-b1aa-3a896d6a1583' | System | 11 Sep 2020 02:21:00 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 11 Sep 2020 02:21:00 |

US3762161

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 26 Nov 2020 11:14:36

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

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-03T14:32:50', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '9d08d977-c8f8-4836-b1aa-3a896d6a1583' | System | 11 Sep 2020 02:21:00 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 11 Sep 2020 02:21:00 |

US3762161

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 26 Nov 2020 11:14:36

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 (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-03T14:32:58', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '9d08d977-c8f8-4836-b1aa-3a896d6a1583' | System | 11 Sep 2020 02:21:00 |
| User entered 'None (1)'                                                                                                                                                                                                                                        | System | 11 Sep 2020 02:21:00 |



**US3762161**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 11:14:36**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-03T14:33:03', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '9d08d977-c8f8-4836-b1aa-3a896d6a1583' | System | 11 Sep 2020 02:21:00 |
| User entered '03 Sep 2020 14:33'                                                                                                                                                                                                                               | System | 11 Sep 2020 02:21:00 |

US3762161

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 11:14:36**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '03 Sep 2020 12:00' | System | 02 Sep 2020 19:29:34 |

US3762161

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 11:14:36**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '04 Sep 2020 11:59' | System | 02 Sep 2020 19:29:34 |

US3762161

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 26 Nov 2020 11:14:36

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 02 Sep 2020 19:29:34 |
| User entered 'Day 3' | System | 02 Sep 2020 19:29:34 |

US3762161

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 26 Nov 2020 11:14:36

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 (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-04T21:08:31', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '138b3fcc-2581-4f87-b2ed-805dc2aeb3f5' | System | 11 Sep 2020 02:21:06 |
| User entered 'None (1)'                                                                                                                                                                                                                                        | System | 11 Sep 2020 02:21:06 |

US3762161

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 26 Nov 2020 11:14:36

Is there any REDNESS AT INJECTION SITE?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-04T21:08:35', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '138b3fcc-2581-4f87-b2ed-805dc2aeb3f5' | System | 11 Sep 2020 02:21:06 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 11 Sep 2020 02:21:06 |

US3762161

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 26 Nov 2020 11:14:36

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

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-04T21:08:39', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '138b3fcc-2581-4f87-b2ed-805dc2aeb3f5' | System | 11 Sep 2020 02:21:06 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 11 Sep 2020 02:21:06 |

US3762161

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 26 Nov 2020 11:14:36

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 (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-04T21:08:46', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '138b3fcc-2581-4f87-b2ed-805dc2aeb3f5' | System | 11 Sep 2020 02:21:06 |
| User entered 'None (1)'                                                                                                                                                                                                                                        | System | 11 Sep 2020 02:21:06 |



US3762161

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 26 Nov 2020 11:14:36

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-04T21:08:49', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '138b3fcc-2581-4f87-b2ed-805dc2aeb3f5' | System | 11 Sep 2020 02:21:06 |
| User entered '04 Sep 2020 21:08'                                                                                                                                                                                                                               | System | 11 Sep 2020 02:21:06 |

US3762161

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 11:14:36**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '04 Sep 2020 12:00' | System | 02 Sep 2020 19:29:34 |

US3762161

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 11:14:36**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '05 Sep 2020 11:59' | System | 02 Sep 2020 19:29:34 |

US3762161

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 26 Nov 2020 11:14:36

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 02 Sep 2020 19:29:34 |
| User entered 'Day 4' | System | 02 Sep 2020 19:29:34 |

US3762161

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 26 Nov 2020 11:14:36

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 (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-05T21:58:11', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '2b06f3b0-2db8-4bab-a904-aaf779016f58' | System | 11 Sep 2020 02:21:07 |
| User entered 'None (1)'                                                                                                                                                                                                                                        | System | 11 Sep 2020 02:21:07 |

US3762161

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 26 Nov 2020 11:14:36

Is there any REDNESS AT INJECTION SITE?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-05T21:58:16', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '2b06f3b0-2db8-4bab-a904-aaf779016f58' | System | 11 Sep 2020 02:21:07 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 11 Sep 2020 02:21:07 |

US3762161

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 26 Nov 2020 11:14:36

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

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-05T21:58:21', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '2b06f3b0-2db8-4bab-a904-aaf779016f58' | System | 11 Sep 2020 02:21:07 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 11 Sep 2020 02:21:07 |

US3762161

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 26 Nov 2020 11:14:36

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 (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-05T21:58:28', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '2b06f3b0-2db8-4bab-a904-aaf779016f58' | System | 11 Sep 2020 02:21:07 |
| User entered 'None (1)'                                                                                                                                                                                                                                        | System | 11 Sep 2020 02:21:07 |



**US3762161**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 11:14:36**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-05T21:58:31', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '2b06f3b0-2db8-4bab-a904-aaf779016f58' | System | 11 Sep 2020 02:21:07 |
| User entered '05 Sep 2020 21:58'                                                                                                                                                                                                                               | System | 11 Sep 2020 02:21:07 |

US3762161

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 11:14:36**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '05 Sep 2020 12:00' | System | 02 Sep 2020 19:29:34 |

US3762161

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 11:14:36**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '06 Sep 2020 11:59' | System | 02 Sep 2020 19:29:34 |

US3762161

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 26 Nov 2020 11:14:36

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 02 Sep 2020 19:29:34 |
| User entered 'Day 5' | System | 02 Sep 2020 19:29:34 |

US3762161

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 26 Nov 2020 11:14:36

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 (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-06T22:53:49', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: 'a49a7dac-830c-41ee-bf4e-7eaf7dc9c8ac' | System | 11 Sep 2020 02:21:08 |
| User entered 'None (1)'                                                                                                                                                                                                                                        | System | 11 Sep 2020 02:21:08 |

US3762161

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 26 Nov 2020 11:14:36

Is there any REDNESS AT INJECTION SITE?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-06T22:53:53', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: 'a49a7dac-830c-41ee-bf4e-7eaf7dc9c8ac' | System | 11 Sep 2020 02:21:08 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 11 Sep 2020 02:21:08 |

US3762161

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 26 Nov 2020 11:14:36

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

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-06T22:53:57', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: 'a49a7dac-830c-41ee-bf4e-7eaf7dc9c8ac' | System | 11 Sep 2020 02:21:08 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 11 Sep 2020 02:21:08 |

US3762161

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 26 Nov 2020 11:14:36

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 (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-06T22:54:04', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: 'a49a7dac-830c-41ee-bf4e-7eaf7dc9c8ac' | System | 11 Sep 2020 02:21:08 |
| User entered 'None (1)'                                                                                                                                                                                                                                        | System | 11 Sep 2020 02:21:08 |



**US3762161**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 11:14:36**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-06T22:54:06', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: 'a49a7dac-830c-41ee-bf4e-7eaf7dc9c8ac' | System | 11 Sep 2020 02:21:08 |
| User entered '06 Sep 2020 22:54'                                                                                                                                                                                                                               | System | 11 Sep 2020 02:21:08 |

US3762161

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 11:14:36**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '06 Sep 2020 12:00' | System | 02 Sep 2020 19:29:34 |

US3762161

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 11:14:36**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '07 Sep 2020 11:59' | System | 02 Sep 2020 19:29:34 |

US3762161

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 26 Nov 2020 11:14:36

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 02 Sep 2020 19:29:34 |
| User entered 'Day 6' | System | 02 Sep 2020 19:29:34 |

US3762161

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 26 Nov 2020 11:14:36

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 (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-07T21:40:09', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '2284a38d-f331-4c76-88b2-48c16bd9c03c' | System | 11 Sep 2020 02:21:13 |
| User entered 'None (1)'                                                                                                                                                                                                                                        | System | 11 Sep 2020 02:21:13 |

US3762161

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 26 Nov 2020 11:14:36

Is there any REDNESS AT INJECTION SITE?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-07T21:40:12', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '2284a38d-f331-4c76-88b2-48c16bd9c03c' | System | 11 Sep 2020 02:21:13 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 11 Sep 2020 02:21:13 |

US3762161

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 26 Nov 2020 11:14:36

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

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-07T21:40:16', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '2284a38d-f331-4c76-88b2-48c16bd9c03c' | System | 11 Sep 2020 02:21:13 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 11 Sep 2020 02:21:13 |

US3762161

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 26 Nov 2020 11:14:36

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 (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-07T21:40:23', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '2284a38d-f331-4c76-88b2-48c16bd9c03c' | System | 11 Sep 2020 02:21:13 |
| User entered 'None (1)'                                                                                                                                                                                                                                        | System | 11 Sep 2020 02:21:13 |



US3762161

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 26 Nov 2020 11:14:36

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-07T21:40:26', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '2284a38d-f331-4c76-88b2-48c16bd9c03c' | System | 11 Sep 2020 02:21:13 |
| User entered '07 Sep 2020 21:40'                                                                                                                                                                                                                               | System | 11 Sep 2020 02:21:13 |

US3762161

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 11:14:36**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '07 Sep 2020 12:00' | System | 02 Sep 2020 19:29:34 |

US3762161

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 11:14:36**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '08 Sep 2020 11:59' | System | 02 Sep 2020 19:29:34 |

US3762161

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 26 Nov 2020 11:14:36

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 02 Sep 2020 19:29:34 |
| User entered 'Day 7' | System | 02 Sep 2020 19:29:34 |

US3762161

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 26 Nov 2020 11:14:36

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 (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-08T22:47:15', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: 'a59d6c61-e19e-41e4-bd14-7cd9716b60bc' | System | 11 Sep 2020 02:21:14 |
| User entered 'None (1)'                                                                                                                                                                                                                                        | System | 11 Sep 2020 02:21:14 |

US3762161

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 26 Nov 2020 11:14:36

Is there any REDNESS AT INJECTION SITE?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-08T22:47:18', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: 'a59d6c61-e19e-41e4-bd14-7cd9716b60bc' | System | 11 Sep 2020 02:21:14 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 11 Sep 2020 02:21:14 |

US3762161

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 26 Nov 2020 11:14:36

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

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-08T22:47:21', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: 'a59d6c61-e19e-41e4-bd14-7cd9716b60bc' | System | 11 Sep 2020 02:21:14 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 11 Sep 2020 02:21:14 |

US3762161

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 26 Nov 2020 11:14:36

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 (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-08T22:47:25', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: 'a59d6c61-e19e-41e4-bd14-7cd9716b60bc' | System | 11 Sep 2020 02:21:14 |
| User entered 'None (1)'                                                                                                                                                                                                                                        | System | 11 Sep 2020 02:21:14 |



**US3762161**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 11:14:36**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-08T22:47:27', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: 'a59d6c61-e19e-41e4-bd14-7cd9716b60bc' | System | 11 Sep 2020 02:21:14 |
| User entered '08 Sep 2020 22:47'                                                                                                                                                                                                                               | System | 11 Sep 2020 02:21:14 |

US3762161

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 11:14:36**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '08 Sep 2020 12:00' | System | 02 Sep 2020 19:29:34 |

US3762161

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 11:14:36**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '09 Sep 2020 11:59' | System | 02 Sep 2020 19:29:34 |

US3762161

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 11:14:36

**TIMEPOINT**

| Audit                                                                | User   | Time (GMT)           |
|----------------------------------------------------------------------|--------|----------------------|
| Data entry locked.                                                   | System | 02 Sep 2020 19:29:34 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 02 Sep 2020 19:29:34 |

US3762161

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 11:14:36

**HEADACHE**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-02T15:57:59', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '99dcdb88-d24b-46e6-a28b-501ee28b95a2' | System | 02 Sep 2020 19:58:24 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 02 Sep 2020 19:58:24 |

US3762161

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 11:14:36

**FATIGUE**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-02T15:57:50', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '99dcdb88-d24b-46e6-a28b-501ee28b95a2' | System | 02 Sep 2020 19:58:24 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 02 Sep 2020 19:58:24 |

US3762161

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 11:14:36

**MUSCLE ACHES ALL OVER BODY**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-02T15:58:03', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '99dcdb88-d24b-46e6-a28b-501ee28b95a2' | System | 02 Sep 2020 19:58:24 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 02 Sep 2020 19:58:24 |

US3762161

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 11:14:36

**JOINT ACHES IN SEVERAL JOINTS**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-02T15:58:07', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '99dcdb88-d24b-46e6-a28b-501ee28b95a2' | System | 02 Sep 2020 19:58:24 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 02 Sep 2020 19:58:24 |



**US3762161**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 11:14:36**

**NAUSEA/VOMITING**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-02T15:58:10', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '99dcdb88-d24b-46e6-a28b-501ee28b95a2' | System | 02 Sep 2020 19:58:24 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 02 Sep 2020 19:58:24 |

US3762161

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 11:14:36

**CHILLS**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-02T15:58:13', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '99dcdb88-d24b-46e6-a28b-501ee28b95a2' | System | 02 Sep 2020 19:58:24 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 02 Sep 2020 19:58:24 |

US3762161

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 11:14:36

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 (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-02T15:58:19', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '99dcdb88-d24b-46e6-a28b-501ee28b95a2' | System | 02 Sep 2020 19:58:24 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 02 Sep 2020 19:58:24 |

**US3762161**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 11:14:36**

[PC Time stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-02T15:58:22', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '99dcdb88-d24b-46e6-a28b-501ee28b95a2' | System | 02 Sep 2020 19:58:24 |
| User entered '02 Sep 2020 15:58'                                                                                                                                                                                                                               | System | 02 Sep 2020 19:58:24 |

US3762161

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 11:14:36**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '02 Sep 2020 15:32' | System | 02 Sep 2020 19:29:34 |

US3762161

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 11:14:36

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '02 Sep 2020 18:02' | System | 02 Sep 2020 19:29:34 |

US3762161

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 11:14:36

**TIMEPOINT**

| Audit                                             | User   | Time (GMT)           |
|---------------------------------------------------|--------|----------------------|
| Data entry locked.                                | System | 02 Sep 2020 19:29:34 |
| User entered 'Day 1, after vaccination (at home)' | System | 02 Sep 2020 19:29:34 |

US3762161

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 11:14:36

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '02 Sep 2020 18:57' | System | 02 Sep 2020 19:29:34 |



US3762161

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 11:14:36**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '03 Sep 2020 11:59' | System | 02 Sep 2020 19:29:34 |

US3762161

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 11:14:36

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 02 Sep 2020 19:29:34 |
| User entered 'Day 2' | System | 02 Sep 2020 19:29:34 |

US3762161

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 11:14:36

**HEADACHE**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-03T14:33:09', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '607c4e5f-8be2-409b-a009-1288e4675c2d' | System | 11 Sep 2020 02:21:04 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 11 Sep 2020 02:21:04 |

US3762161

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 11:14:36

**FATIGUE**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-03T14:33:13', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '607c4e5f-8be2-409b-a009-1288e4675c2d' | System | 11 Sep 2020 02:21:04 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 11 Sep 2020 02:21:04 |

US3762161

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 11:14:36

**MUSCLE ACHES ALL OVER BODY**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-03T14:33:17', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '607c4e5f-8be2-409b-a009-1288e4675c2d' | System | 11 Sep 2020 02:21:04 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 11 Sep 2020 02:21:04 |

US3762161

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 11:14:36

**JOINT ACHES IN SEVERAL JOINTS**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-03T14:33:20', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '607c4e5f-8be2-409b-a009-1288e4675c2d' | System | 11 Sep 2020 02:21:04 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 11 Sep 2020 02:21:04 |

US3762161

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 11:14:36

**NAUSEA/VOMITING**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-03T14:33:23', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '607c4e5f-8be2-409b-a009-1288e4675c2d' | System | 11 Sep 2020 02:21:04 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 11 Sep 2020 02:21:04 |

US3762161

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 11:14:36

**CHILLS**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-03T14:33:27', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '607c4e5f-8be2-409b-a009-1288e4675c2d' | System | 11 Sep 2020 02:21:04 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 11 Sep 2020 02:21:04 |



US3762161

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 11:14:36

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 (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-03T14:33:31', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '607c4e5f-8be2-409b-a009-1288e4675c2d' | System | 11 Sep 2020 02:21:04 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 11 Sep 2020 02:21:04 |

US3762161

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 11:14:36

[PC Time stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-03T14:33:35', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '607c4e5f-8be2-409b-a009-1288e4675c2d' | System | 11 Sep 2020 02:21:04 |
| User entered '03 Sep 2020 14:33'                                                                                                                                                                                                                               | System | 11 Sep 2020 02:21:04 |

US3762161

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 11:14:36

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '03 Sep 2020 12:00' | System | 02 Sep 2020 19:29:34 |

US3762161

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 11:14:36**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '04 Sep 2020 11:59' | System | 02 Sep 2020 19:29:34 |

US3762161

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 11:14:36

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 02 Sep 2020 19:29:34 |
| User entered 'Day 3' | System | 02 Sep 2020 19:29:34 |

**US3762161**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 11:14:36**

**HEADACHE**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-04T21:08:56', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '87892a4e-a147-47e4-a69b-750419bffb30' | System | 11 Sep 2020 02:21:06 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 11 Sep 2020 02:21:06 |

US3762161

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 11:14:36

**FATIGUE**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-04T21:09:00', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '87892a4e-a147-47e4-a69b-750419bffb30' | System | 11 Sep 2020 02:21:06 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 11 Sep 2020 02:21:06 |

US3762161

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 11:14:36

**MUSCLE ACHES ALL OVER BODY**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-04T21:09:04', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '87892a4e-a147-47e4-a69b-750419bffb30' | System | 11 Sep 2020 02:21:06 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 11 Sep 2020 02:21:06 |



US3762161

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 11:14:36

**JOINT ACHES IN SEVERAL JOINTS**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-04T21:09:08', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '87892a4e-a147-47e4-a69b-750419bffb30' | System | 11 Sep 2020 02:21:06 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 11 Sep 2020 02:21:06 |

US3762161

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 11:14:36

**NAUSEA/VOMITING**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-04T21:09:11', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '87892a4e-a147-47e4-a69b-750419bffb30' | System | 11 Sep 2020 02:21:06 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 11 Sep 2020 02:21:06 |

US3762161

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 11:14:36

**CHILLS**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-04T21:09:15', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '87892a4e-a147-47e4-a69b-750419bffb30' | System | 11 Sep 2020 02:21:06 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 11 Sep 2020 02:21:06 |

US3762161

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 11:14:36

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 (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-04T21:09:20', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '87892a4e-a147-47e4-a69b-750419bffb30' | System | 11 Sep 2020 02:21:06 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 11 Sep 2020 02:21:06 |

US3762161

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 11:14:36

[PC Time stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-04T21:09:23', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '87892a4e-a147-47e4-a69b-750419bffb30' | System | 11 Sep 2020 02:21:06 |
| User entered '04 Sep 2020 21:09'                                                                                                                                                                                                                               | System | 11 Sep 2020 02:21:06 |

US3762161

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 11:14:36

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '04 Sep 2020 12:00' | System | 02 Sep 2020 19:29:34 |

US3762161

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 11:14:36

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '05 Sep 2020 11:59' | System | 02 Sep 2020 19:29:34 |

**US3762161**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 11:14:36**

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 02 Sep 2020 19:29:34 |
| User entered 'Day 4' | System | 02 Sep 2020 19:29:34 |



US3762161

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 11:14:36

**HEADACHE**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-05T21:58:37', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '02e34d48-493b-4415-a60c-4d7e9ceba5cb' | System | 11 Sep 2020 02:21:08 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 11 Sep 2020 02:21:08 |

US3762161

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 11:14:36

**FATIGUE**

| Audit                                                                                                                                                                                                                                                                                  | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-05T21:58:40', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '02e34d48-493b-4415-a60c-4d7e9ceba5cb' User entered 'None (0)' | System | 11 Sep 2020 02:21:08 |
|                                                                                                                                                                                                                                                                                        | System | 11 Sep 2020 02:21:08 |

US3762161

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 11:14:36

**MUSCLE ACHES ALL OVER BODY**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-05T21:58:43', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '02e34d48-493b-4415-a60c-4d7e9ceba5cb' | System | 11 Sep 2020 02:21:08 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 11 Sep 2020 02:21:08 |

US3762161

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 11:14:36

**JOINT ACHES IN SEVERAL JOINTS**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-05T21:58:46', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '02e34d48-493b-4415-a60c-4d7e9ceba5cb' | System | 11 Sep 2020 02:21:08 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 11 Sep 2020 02:21:08 |

US3762161

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 11:14:36

**NAUSEA/VOMITING**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-05T21:58:49', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '02e34d48-493b-4415-a60c-4d7e9ceba5cb' | System | 11 Sep 2020 02:21:08 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 11 Sep 2020 02:21:08 |

US3762161

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 11:14:36

**CHILLS**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-05T21:58:53', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '02e34d48-493b-4415-a60c-4d7e9ceba5cb' | System | 11 Sep 2020 02:21:08 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 11 Sep 2020 02:21:08 |

US3762161

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 11:14:36

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 (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-05T21:59:06', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '02e34d48-493b-4415-a60c-4d7e9ceba5cb' | System | 11 Sep 2020 02:21:08 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 11 Sep 2020 02:21:08 |

US3762161

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 11:14:36

[PC Time stamp](#)

| Audit                                                                                                                                                                                                                                                                                           | User   | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-05T21:59:09', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '02e34d48-493b-4415-a60c-4d7e9ceba5cb' User entered '05 Sep 2020 21:59' | System | 11 Sep 2020 02:21:08 |
|                                                                                                                                                                                                                                                                                                 | System | 11 Sep 2020 02:21:08 |



US3762161

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 11:14:36

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '05 Sep 2020 12:00' | System | 02 Sep 2020 19:29:34 |

US3762161

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 11:14:36

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '06 Sep 2020 11:59' | System | 02 Sep 2020 19:29:34 |

US3762161

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 11:14:36

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 02 Sep 2020 19:29:34 |
| User entered 'Day 5' | System | 02 Sep 2020 19:29:34 |

US3762161

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 11:14:36

**HEADACHE**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-06T22:54:12', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '6b359e3a-7267-43e2-a1d1-ce8d2c15493c' | System | 11 Sep 2020 02:21:11 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 11 Sep 2020 02:21:11 |

US3762161

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 11:14:36

**FATIGUE**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-06T22:54:15', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '6b359e3a-7267-43e2-a1d1-ce8d2c15493c' | System | 11 Sep 2020 02:21:11 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 11 Sep 2020 02:21:11 |

US3762161

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 11:14:36

**MUSCLE ACHES ALL OVER BODY**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-06T22:54:19', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '6b359e3a-7267-43e2-a1d1-ce8d2c15493c' | System | 11 Sep 2020 02:21:11 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 11 Sep 2020 02:21:11 |

US3762161

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 11:14:36

**JOINT ACHES IN SEVERAL JOINTS**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-06T22:54:29', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '6b359e3a-7267-43e2-a1d1-ce8d2c15493c' | System | 11 Sep 2020 02:21:11 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 11 Sep 2020 02:21:11 |

US3762161

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 11:14:36

**NAUSEA/VOMITING**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-06T22:54:32', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '6b359e3a-7267-43e2-a1d1-ce8d2c15493c' | System | 11 Sep 2020 02:21:11 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 11 Sep 2020 02:21:11 |



US3762161

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 11:14:36

**CHILLS**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-06T22:54:35', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '6b359e3a-7267-43e2-a1d1-ce8d2c15493c' | System | 11 Sep 2020 02:21:11 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 11 Sep 2020 02:21:11 |

US3762161

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 11:14:36

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 (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-06T22:54:41', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '6b359e3a-7267-43e2-a1d1-ce8d2c15493c' | System | 11 Sep 2020 02:21:11 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 11 Sep 2020 02:21:11 |

**US3762161**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 11:14:36**

[PC Time stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-06T22:54:43', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '6b359e3a-7267-43e2-a1d1-ce8d2c15493c' | System | 11 Sep 2020 02:21:11 |
| User entered '06 Sep 2020 22:54'                                                                                                                                                                                                                               | System | 11 Sep 2020 02:21:11 |

US3762161

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 11:14:36

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '06 Sep 2020 12:00' | System | 02 Sep 2020 19:29:34 |

US3762161

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 11:14:36

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '07 Sep 2020 11:59' | System | 02 Sep 2020 19:29:34 |

**US3762161**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 11:14:36**

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 02 Sep 2020 19:29:34 |
| User entered 'Day 6' | System | 02 Sep 2020 19:29:34 |

US3762161

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 11:14:36

**HEADACHE**

| Audit                                                                                                                                                                                                                                                                                  | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-07T21:40:39', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: 'f5afb5d2-1979-4098-9b97-64ac3dc094bb' User entered 'None (0)' | System | 11 Sep 2020 02:21:13 |
|                                                                                                                                                                                                                                                                                        | System | 11 Sep 2020 02:21:13 |

US3762161

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 11:14:36

**FATIGUE**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-07T21:40:42', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: 'f5afb5d2-1979-4098-9b97-64ac3dc094bb' | System | 11 Sep 2020 02:21:13 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 11 Sep 2020 02:21:13 |



US3762161

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 11:14:36

**MUSCLE ACHES ALL OVER BODY**

| Audit                                                                                                                                                                                                                                                                                  | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-07T21:40:45', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: 'f5afb5d2-1979-4098-9b97-64ac3dc094bb' User entered 'None (0)' | System | 11 Sep 2020 02:21:13 |
|                                                                                                                                                                                                                                                                                        | System | 11 Sep 2020 02:21:13 |

US3762161

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 11:14:36

**JOINT ACHES IN SEVERAL JOINTS**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-07T21:40:50', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: 'f5afb5d2-1979-4098-9b97-64ac3dc094bb' | System | 11 Sep 2020 02:21:13 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 11 Sep 2020 02:21:13 |

US3762161

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 11:14:36

**NAUSEA/VOMITING**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-07T21:40:52', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: 'f5afb5d2-1979-4098-9b97-64ac3dc094bb' | System | 11 Sep 2020 02:21:13 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 11 Sep 2020 02:21:13 |

US3762161

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 11:14:36

**CHILLS**

| Audit                                                                                                                                                                                                                                                                                  | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-07T21:40:55', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: 'f5afb5d2-1979-4098-9b97-64ac3dc094bb' User entered 'None (0)' | System | 11 Sep 2020 02:21:13 |
|                                                                                                                                                                                                                                                                                        | System | 11 Sep 2020 02:21:13 |

US3762161

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 11:14:36

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 (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-07T21:40:59', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: 'f5afb5d2-1979-4098-9b97-64ac3dc094bb' | System | 11 Sep 2020 02:21:13 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 11 Sep 2020 02:21:13 |

**US3762161**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 11:14:36**

[PC Time stamp](#)

| Audit                                                                                                                                                                                                                                                                                           | User   | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-07T21:41:02', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: 'f5afb5d2-1979-4098-9b97-64ac3dc094bb' User entered '07 Sep 2020 21:41' | System | 11 Sep 2020 02:21:13 |
|                                                                                                                                                                                                                                                                                                 | System | 11 Sep 2020 02:21:13 |

US3762161

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 11:14:36

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '07 Sep 2020 12:00' | System | 02 Sep 2020 19:29:34 |

US3762161

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 11:14:36**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '08 Sep 2020 11:59' | System | 02 Sep 2020 19:29:34 |



US3762161

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 11:14:36

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 02 Sep 2020 19:29:34 |
| User entered 'Day 7' | System | 02 Sep 2020 19:29:34 |

US3762161

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 11:14:36

**HEADACHE**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-08T22:47:32', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: 'b1756140-ce87-4d67-87d9-4013973d9eda' | System | 11 Sep 2020 02:21:15 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 11 Sep 2020 02:21:15 |

US3762161

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 11:14:36

**FATIGUE**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-08T22:47:34', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: 'b1756140-ce87-4d67-87d9-4013973d9eda' | System | 11 Sep 2020 02:21:15 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 11 Sep 2020 02:21:15 |

US3762161

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 11:14:36

**MUSCLE ACHES ALL OVER BODY**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-08T22:47:37', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: 'b1756140-ce87-4d67-87d9-4013973d9eda' | System | 11 Sep 2020 02:21:15 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 11 Sep 2020 02:21:15 |

US3762161

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 11:14:36

**JOINT ACHES IN SEVERAL JOINTS**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-08T22:47:40', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: 'b1756140-ce87-4d67-87d9-4013973d9eda' | System | 11 Sep 2020 02:21:15 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 11 Sep 2020 02:21:15 |

**US3762161**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 11:14:36**

**NAUSEA/VOMITING**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-08T22:47:42', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: 'b1756140-ce87-4d67-87d9-4013973d9eda' | System | 11 Sep 2020 02:21:15 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 11 Sep 2020 02:21:15 |

US3762161

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 11:14:36

CHILLS

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-08T22:47:45', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: 'b1756140-ce87-4d67-87d9-4013973d9eda' | System | 11 Sep 2020 02:21:15 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 11 Sep 2020 02:21:15 |

US3762161

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 11:14:36

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 (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-08T22:47:49', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: 'b1756140-ce87-4d67-87d9-4013973d9eda' | System | 11 Sep 2020 02:21:15 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 11 Sep 2020 02:21:15 |



**US3762161**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 11:14:36**

[PC Time stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-08T22:47:51', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: 'b1756140-ce87-4d67-87d9-4013973d9eda' | System | 11 Sep 2020 02:21:15 |
| User entered '08 Sep 2020 22:47'                                                                                                                                                                                                                               | System | 11 Sep 2020 02:21:15 |

US3762161

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 11:14:36

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '08 Sep 2020 12:00' | System | 02 Sep 2020 19:29:34 |

US3762161

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 11:14:36

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '09 Sep 2020 11:59' | System | 02 Sep 2020 19:29:34 |

US3762161

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:14:36

[Was Contact Attempted?](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 30 Sep 2020 20:24:04 |
|                        |                  |                      |

US3762161

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:14:36

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

| Audit                                                          | User             | Time (GMT)           |
|----------------------------------------------------------------|------------------|----------------------|
| User entered '09 Sep 2020' reason for change: Data Entry Error | (b) (4), (b) (6) | 10 Nov 2020 14:44:47 |
| User entered '9 Sep 2020'                                      | (b) (4), (b) (6) | 30 Sep 2020 20:24:04 |

US3762161

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:14:36

[Please select one status for the follow-up contact](#)

| Audit                                      | User             | Time (GMT)           |
|--------------------------------------------|------------------|----------------------|
| User entered 'Contact Made (CONTACT MADE)' | (b) (4), (b) (6) | 30 Sep 2020 20:24:04 |
|                                            |                  |                      |

US3762161

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:14:36

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 30 Sep 2020 20:24:04 |
|                     |                  |                      |

US3762161

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:14:36

[Is the participant continuing to the next visit?](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 30 Sep 2020 20:24:09 |
|                        |                  |                      |



**US3762161**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 11:14:36**

[Continuing Flag](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 30 Sep 2020 20:24:09 |

US3762161

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:14:36

[Was Contact Attempted?](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 30 Sep 2020 20:24:27 |
|                        |                  |                      |

US3762161

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:14:36

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

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| User entered '16 Sep 2020' | (b) (4), (b) (6) | 30 Sep 2020 20:24:27 |
|                            |                  |                      |

US3762161

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:14:36

[Please select one status for the follow-up contact](#)

| Audit                                      | User             | Time (GMT)           |
|--------------------------------------------|------------------|----------------------|
| User entered 'Contact Made (CONTACT MADE)' | (b) (4), (b) (6) | 30 Sep 2020 20:24:27 |

**US3762161**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 11:14:36**

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 30 Sep 2020 20:24:27 |
|                     |                  |                      |

US3762161

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:14:36

[Is the participant continuing to the next visit?](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 30 Sep 2020 20:24:43 |
|                        |                  |                      |

**US3762161**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 11:14:36**

[Continuing Flag](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 30 Sep 2020 20:24:43 |

US3762161

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:14:36

[Was Contact Attempted?](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 30 Sep 2020 20:24:56 |
|                        |                  |                      |



US3762161

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:14:36

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

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| User entered '23 Sep 2020' | (b) (4), (b) (6) | 30 Sep 2020 20:24:56 |
|                            |                  |                      |

US3762161

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:14:36

[Please select one status for the follow-up contact](#)

| Audit                                      | User             | Time (GMT)           |
|--------------------------------------------|------------------|----------------------|
| User entered 'Contact Made (CONTACT MADE)' | (b) (4), (b) (6) | 30 Sep 2020 20:24:56 |
|                                            |                  |                      |

US3762161

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:14:36

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 30 Sep 2020 20:24:56 |
|                     |                  |                      |

US3762161

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:14:36

[Is the participant continuing to the next visit?](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 30 Sep 2020 20:25:02 |
|                        |                  |                      |

**US3762161**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 11:14:36**

[Continuing Flag](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 30 Sep 2020 20:25:02 |

US3762161

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:14:36

[Was this visit performed?](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 30 Sep 2020 20:25:19 |
|                        |                  |                      |

US3762161

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:14:36

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

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| User entered '30 Sep 2020' | (b) (4), (b) (6) | 30 Sep 2020 20:25:19 |
|                            |                  |                      |

US3762161

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:14:36

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

| Audit                          | User             | Time (GMT)           |
|--------------------------------|------------------|----------------------|
| User entered 'Clinic (Clinic)' | (b) (4), (b) (6) | 30 Sep 2020 20:25:19 |
|                                |                  |                      |



**US3762161**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 26 Nov 2020 11:14:36**

[Folder OID](#)

| Audit                 | User   | Time (GMT)           |
|-----------------------|--------|----------------------|
| User entered 'VISIT2' | System | 30 Sep 2020 20:25:19 |

US3762161

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:14:36

[Timepoint](#)

| Audit                                            | User                             | Time (GMT)           |
|--------------------------------------------------|----------------------------------|----------------------|
| User accepted default value 'Pre-Dose (PREDOSE)' | James Lovette (b) (4)<br>(b) (4) | 01 Oct 2020 20:22:49 |

US3762161

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:14:36

[Were vital signs assessed?](#)

| Audit                  | User                             | Time (GMT)           |
|------------------------|----------------------------------|----------------------|
| User entered 'Yes (Y)' | James Lovette (b) (4)<br>(b) (4) | 01 Oct 2020 20:22:49 |

US3762161

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:14:36

Date of assessment (*dd MMM yyyy*)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| User entered '30 Sep 2020' | James Lovette (b) (4)<br>(b) (4) | 01 Oct 2020 20:22:49 |

US3762161

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:14:36

Time of assessment (00:00-23:59)

| Audit                | User                             | Time (GMT)           |
|----------------------|----------------------------------|----------------------|
| User entered '15:13' | James Lovette (b) (4)<br>(b) (4) | 01 Oct 2020 20:22:49 |

US3762161

**Folder: Visit 2 Day 29 (1)**

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

**Generated On: 26 Nov 2020 11:14:36**

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

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '30 Sep 2020 15:13' | System | 01 Oct 2020 20:22:49 |

US3762161

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:14:36

Temperature (xxx.x)

| Audit                 | User                             | Time (GMT)           |
|-----------------------|----------------------------------|----------------------|
| User entered '98.9' F | James Lovette (b) (4)<br>(b) (4) | 01 Oct 2020 20:22:49 |

US3762161

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:14:36

[Route of measurement](#)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| User entered 'Oral (Oral)' | James Lovette (b) (4)<br>(b) (4) | 01 Oct 2020 20:22:49 |



US3762161

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:14:36

[If Other, specify](#)

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| User entered empty. | James Lovette (b) (4)<br>(b) (4) | 01 Oct 2020 20:22:49 |

US3762161

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:14:36

Pulse (xxx)

| Audit             | User                             | Time (GMT)           |
|-------------------|----------------------------------|----------------------|
| User entered '81' | James Lovette (b) (4)<br>(b) (4) | 01 Oct 2020 20:22:49 |

US3762161

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:14:36

[Pulse units](#)

| Audit              | User   | Time (GMT)           |
|--------------------|--------|----------------------|
| User entered 'bpm' | System | 01 Oct 2020 20:22:49 |

US3762161

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:14:36

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

| Audit             | User                             | Time (GMT)           |
|-------------------|----------------------------------|----------------------|
| User entered '15' | James Lovette (b) (4)<br>(b) (4) | 01 Oct 2020 20:22:49 |

US3762161

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:14:36

[Respiratory Rate units](#)

| Audit                      | User   | Time (GMT)           |
|----------------------------|--------|----------------------|
| User entered 'breaths/min' | System | 01 Oct 2020 20:22:49 |

US3762161

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:14:36

Systolic Blood Pressure (xxx)

| Audit              | User                             | Time (GMT)           |
|--------------------|----------------------------------|----------------------|
| User entered '121' | James Lovette (b) (4)<br>(b) (4) | 01 Oct 2020 20:22:49 |

US3762161

**Folder: Visit 2 Day 29 (1)**

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

**Generated On: 26 Nov 2020 11:14:36**

[Systolic Blood Pressure units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 01 Oct 2020 20:22:49 |

US3762161

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:14:36

Diastolic Blood Pressure (xxx)

| Audit             | User                             | Time (GMT)           |
|-------------------|----------------------------------|----------------------|
| User entered '70' | James Lovette (b) (4)<br>(b) (4) | 01 Oct 2020 20:22:49 |



US3762161

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:14:36

[Diastolic Blood Pressure units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 01 Oct 2020 20:22:49 |

US3762161

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:14:36

[Timepoint](#)

| Audit                                              | User                             | Time (GMT)           |
|----------------------------------------------------|----------------------------------|----------------------|
| User accepted default value 'Post-Dose (POSTDOSE)' | James Lovette (b) (4)<br>(b) (4) | 01 Oct 2020 20:22:49 |

US3762161

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:14:36

[Were vital signs assessed?](#)

| Audit                  | User                             | Time (GMT)           |
|------------------------|----------------------------------|----------------------|
| User entered 'Yes (Y)' | James Lovette (b) (4)<br>(b) (4) | 01 Oct 2020 20:22:49 |

US3762161

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:14:36

Date of assessment (*dd MMM yyyy*)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| User entered '30 Sep 2020' | James Lovette (b) (4)<br>(b) (4) | 01 Oct 2020 20:22:49 |

US3762161

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 11:14:36**

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

| Audit                | User                             | Time (GMT)           |
|----------------------|----------------------------------|----------------------|
| User entered '16:20' | James Lovette (b) (4)<br>(b) (4) | 01 Oct 2020 20:22:49 |

US3762161

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 11:14:36**

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

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '30 Sep 2020 16:20' | System | 01 Oct 2020 20:22:49 |

US3762161

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:14:36

Temperature (xxx.x)

| Audit                 | User                             | Time (GMT)           |
|-----------------------|----------------------------------|----------------------|
| User entered '98.2' F | James Lovette (b) (4)<br>(b) (4) | 01 Oct 2020 20:22:49 |

US3762161

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 11:14:36**

[Route of measurement](#)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| User entered 'Oral (Oral)' | James Lovette (b) (4)<br>(b) (4) | 01 Oct 2020 20:22:49 |



US3762161

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:14:36

[If Other, specify](#)

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| User entered empty. | James Lovette (b) (4)<br>(b) (4) | 01 Oct 2020 20:22:49 |

US3762161

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:14:36

Pulse (xxx)

| Audit             | User                             | Time (GMT)           |
|-------------------|----------------------------------|----------------------|
| User entered '76' | James Lovette (b) (4)<br>(b) (4) | 01 Oct 2020 20:22:49 |

**US3762161**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 11:14:36**

[Pulse units](#)

| Audit              | User   | Time (GMT)           |
|--------------------|--------|----------------------|
| User entered 'bpm' | System | 01 Oct 2020 20:22:49 |

US3762161

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:14:36

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

| Audit                                                                                        | User                  | Time (GMT)           |
|----------------------------------------------------------------------------------------------|-----------------------|----------------------|
| User closed query 'Data is required. Please provide.' (Site from System).                    | System                | 01 Oct 2020 20:23:21 |
| Query 'Data is required. Please provide.' answered by System data change (Site from System). |                       | 01 Oct 2020 20:23:21 |
| User entered missing code ND - Not Done; reason for change Data Entry Error                  | James Lovette (b) (4) | 01 Oct 2020 20:23:21 |
| User opened query 'Data is required. Please provide.' (Site from System).                    | (b) (4)               | 01 Oct 2020 20:22:49 |
| User entered empty.                                                                          | James Lovette (b) (4) | 01 Oct 2020 20:22:49 |

US3762161

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:14:36

[Respiratory Rate units](#)

| Audit                      | User   | Time (GMT)           |
|----------------------------|--------|----------------------|
| User entered 'breaths/min' | System | 01 Oct 2020 20:23:21 |
| User entered empty.        | System | 01 Oct 2020 20:22:49 |

US3762161

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:14:36

Systolic Blood Pressure (xxx)

| Audit              | User                             | Time (GMT)           |
|--------------------|----------------------------------|----------------------|
| User entered '113' | James Lovette (b) (4)<br>(b) (4) | 01 Oct 2020 20:22:49 |

US3762161

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:14:36

[Systolic Blood Pressure units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 01 Oct 2020 20:22:49 |

US3762161

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:14:36

Diastolic Blood Pressure (xxx)

| Audit             | User                             | Time (GMT)           |
|-------------------|----------------------------------|----------------------|
| User entered '64' | James Lovette (b) (4)<br>(b) (4) | 01 Oct 2020 20:22:49 |



US3762161

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:14:36

[Diastolic Blood Pressure units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 01 Oct 2020 20:22:49 |

US3762161

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:14:36

Was the physical examination performed?

| Audit                  | User                             | Time (GMT)           |
|------------------------|----------------------------------|----------------------|
| User entered 'Yes (Y)' | James Lovette (b) (4)<br>(b) (4) | 01 Oct 2020 20:23:38 |

US3762161

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:14:36

Date of examination (dd MMM yyyy)

| Audit                                                                                                                          | User                  | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------|-----------------------|----------------------|
| User closed query 'The Physical Examination Date is not equal to Visit Date. Please review and reconcile.' (Site from System). | System                | 01 Oct 2020 20:23:54 |
| User entered '30 Sep 2020' reason for change: Data Entry Error                                                                 | James Lovette (b) (4) | 01 Oct 2020 20:23:54 |
| User opened query 'The Physical Examination Date is not equal to Visit Date. Please review and reconcile.' (Site from System). | (b) (4)               | 01 Oct 2020 20:23:38 |
| User entered '20 Sep 2020'                                                                                                     | James Lovette (b) (4) | 01 Oct 2020 20:23:38 |

US3762161

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:14:36

[Was study treatment given?](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 30 Sep 2020 20:25:41 |
|                        |                  |                      |

US3762161

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:14:36

[If No, reason not given](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 30 Sep 2020 20:25:41 |
|                     |                  |                      |

US3762161

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:14:36

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 30 Sep 2020 20:25:41 |
|                     |                  |                      |

US3762161

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:14:36

[What was the study treatment?](#)

| Audit                               | User   | Time (GMT)           |
|-------------------------------------|--------|----------------------|
| User entered 'MRNA-1273 OR PLACEBO' | System | 30 Sep 2020 20:25:41 |

US3762161

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:14:36

What was the treatment date? (dd MMM yyyy)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| User entered '30 Sep 2020' | (b) (4), (b) (6) | 30 Sep 2020 20:25:41 |
|                            |                  |                      |



US3762161

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:14:36

[What was the treatment time? \(00:00-23:59\)](#)

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| User entered '15:30' | (b) (4), (b) (6) | 30 Sep 2020 20:25:41 |
|                      |                  |                      |

**US3762161**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 26 Nov 2020 11:14:36**

[Treatment Date and Time \(derived\)](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '30 Sep 2020 15:30' | System | 30 Sep 2020 20:25:41 |

US3762161

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:14:36

[Which arm was used to give treatment?](#)

| Audit                              | User             | Time (GMT)           |
|------------------------------------|------------------|----------------------|
| User entered 'Left Arm (LEFT ARM)' | (b) (4), (b) (6) | 30 Sep 2020 20:25:41 |
|                                    |                  |                      |

US3762161

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:14:36

[What was the frequency of the study treatment dosing?](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'ONCE' | System | 30 Sep 2020 20:25:41 |

US3762161

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:14:36

[What was the route of administration for the study treatment?](#)

| Audit                        | User   | Time (GMT)           |
|------------------------------|--------|----------------------|
| User entered 'INTRAMUSCULAR' | System | 30 Sep 2020 20:25:41 |

US3762161

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:14:36

[Was the sample collected?](#)

| Audit                  | User                             | Time (GMT)           |
|------------------------|----------------------------------|----------------------|
| User entered 'Yes (Y)' | James Lovette (b) (4)<br>(b) (4) | 01 Oct 2020 20:24:11 |

US3762161

**Folder:** Visit 2 Day 29 (1)

**Form:** Immunogenicity Assessment

**Generated On:** 26 Nov 2020 11:14:36

**Collection date** (*dd MMM yyyy*)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| User entered '30 Sep 2020' | James Lovette (b) (4)<br>(b) (4) | 01 Oct 2020 20:24:11 |

US3762161

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:14:36

Collection time (00:00-23:59)

| Audit                | User                             | Time (GMT)           |
|----------------------|----------------------------------|----------------------|
| User entered '15:16' | James Lovette (b) (4)<br>(b) (4) | 01 Oct 2020 20:24:11 |



**US3762161**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 26 Nov 2020 11:14:36**

[Collection date and time \(derived\)](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '30 Sep 2020 15:16' | System | 01 Oct 2020 20:24:11 |

US3762161

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 11:14:36

Collection date (*dd MMM yyyy*)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| User entered '30 Sep 2020' | James Lovette (b) (4)<br>(b) (4) | 01 Oct 2020 20:24:44 |

US3762161

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:14:36

[Lab Test](#)

| Audit                                                        | User                  | Time (GMT)           |
|--------------------------------------------------------------|-----------------------|----------------------|
| User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)' | James Lovette (b) (4) | 01 Oct 2020 20:24:44 |

US3762161

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:14:36

[Was the sample collected?](#)

| Audit                  | User                             | Time (GMT)           |
|------------------------|----------------------------------|----------------------|
| User entered 'Yes (Y)' | James Lovette (b) (4)<br>(b) (4) | 01 Oct 2020 20:24:44 |

US3762161

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:14:36

Collection time (00:00 - 23:59)

| Audit                | User                             | Time (GMT)           |
|----------------------|----------------------------------|----------------------|
| User entered '15:26' | James Lovette (b) (4)<br>(b) (4) | 01 Oct 2020 20:24:44 |

**US3762161**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 26 Nov 2020 11:14:36**

[Collection date and time \(derived\)](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '30 Sep 2020 15:26' | System | 01 Oct 2020 20:24:44 |

US3762161

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:14:36

[Lab Test](#)

| Audit                                                        | User                  | Time (GMT)           |
|--------------------------------------------------------------|-----------------------|----------------------|
| User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)' | James Lovette (b) (4) | 01 Oct 2020 20:24:44 |

US3762161

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:14:36

[Was the sample collected?](#)

| Audit                 | User                             | Time (GMT)           |
|-----------------------|----------------------------------|----------------------|
| User entered 'No (N)' | James Lovette (b) (4)<br>(b) (4) | 01 Oct 2020 20:24:44 |



US3762161

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:14:36

Collection time (00:00 - 23:59)

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| User entered empty. | James Lovette (b) (4)<br>(b) (4) | 01 Oct 2020 20:24:44 |

**US3762161**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 26 Nov 2020 11:14:36**

[Collection date and time \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 01 Oct 2020 20:24:44 |

US3762161

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:14:36

[Is the participant continuing to the next visit?](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 30 Sep 2020 20:25:47 |
|                        |                  |                      |

**US3762161**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 11:14:36**

[Continuing Flag](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 30 Sep 2020 20:25:47 |

US3762161

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 26 Nov 2020 11:14:36

**TIMEPOINT**

| Audit                                                                | User   | Time (GMT)           |
|----------------------------------------------------------------------|--------|----------------------|
| Data entry locked.                                                   | System | 30 Sep 2020 20:25:41 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 30 Sep 2020 20:25:41 |

US3762161

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 26 Nov 2020 11:14:36

Was **TEMPERATURE** taken?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-30T16:26:50', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: 'ee5f18f4-85a4-41df-8320-e0966f122142' | System | 30 Sep 2020 20:27:16 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                                         | System | 30 Sep 2020 20:27:16 |

US3762161

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 26 Nov 2020 11:14:36

Please record your **TEMPERATURE** in °F

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-30T16:27:03', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: 'ee5f18f4-85a4-41df-8320-e0966f122142' | System | 30 Sep 2020 20:27:16 |
| User entered '98.2'                                                                                                                                                                                                                                            | System | 30 Sep 2020 20:27:16 |

US3762161

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 26 Nov 2020 11:14:36

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

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-30T16:27:09', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: 'ee5f18f4-85a4-41df-8320-e0966f122142' | System | 30 Sep 2020 20:27:16 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 30 Sep 2020 20:27:16 |



**US3762161**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 26 Nov 2020 11:14:36**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-30T16:27:15', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: 'ee5f18f4-85a4-41df-8320-e0966f122142' | System | 30 Sep 2020 20:27:16 |
| User entered '30 Sep 2020 16:27'                                                                                                                                                                                                                               | System | 30 Sep 2020 20:27:16 |

US3762161

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 26 Nov 2020 11:14:36

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '30 Sep 2020 15:50' | System | 30 Sep 2020 20:25:41 |

US3762161

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 26 Nov 2020 11:14:36**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '30 Sep 2020 18:20' | System | 30 Sep 2020 20:25:41 |

US3762161

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 26 Nov 2020 11:14:36

**TIMEPOINT**

| Audit                                             | User   | Time (GMT)           |
|---------------------------------------------------|--------|----------------------|
| Data entry locked.                                | System | 30 Sep 2020 20:25:41 |
| User entered 'Day 1, after vaccination (at home)' | System | 30 Sep 2020 20:25:41 |

US3762161

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 26 Nov 2020 11:14:36

Was **TEMPERATURE** taken?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-30T23:04:28', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '37c698ce-aa35-41d2-aa06-cdc076b26c5a' | System | 01 Oct 2020 03:04:54 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                                         | System | 01 Oct 2020 03:04:54 |

US3762161

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 26 Nov 2020 11:14:36

Please record your **TEMPERATURE** in °F

| Audit                                                                                                                                                                                                                                                                              | User   | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-30T23:04:43', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '37c698ce-aa35-41d2-aa06-cdc076b26c5a' User entered '96.2' | System | 01 Oct 2020 03:04:54 |

US3762161

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 26 Nov 2020 11:14:36

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

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-30T23:04:48', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '37c698ce-aa35-41d2-aa06-cdc076b26c5a' | System | 01 Oct 2020 03:04:54 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 01 Oct 2020 03:04:54 |

US3762161

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 26 Nov 2020 11:14:36

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-30T23:04:52', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '37c698ce-aa35-41d2-aa06-cdc076b26c5a' | System | 01 Oct 2020 03:04:54 |
| User entered '30 Sep 2020 23:04'                                                                                                                                                                                                                               | System | 01 Oct 2020 03:04:54 |



US3762161

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 26 Nov 2020 11:14:36**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '30 Sep 2020 19:15' | System | 30 Sep 2020 20:25:41 |

US3762161

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 26 Nov 2020 11:14:36**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '01 Oct 2020 11:59' | System | 30 Sep 2020 20:25:41 |

US3762161

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 11:14:36

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 30 Sep 2020 20:25:41 |
| User entered 'Day 2' | System | 30 Sep 2020 20:25:41 |

US3762161

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 11:14:36

Was **TEMPERATURE** taken?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-02T02:29:17', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: 'bcb0731d-8b3c-4ab4-8264-f1b625a93aea' | System | 02 Oct 2020 06:29:37 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                                         | System | 02 Oct 2020 06:29:37 |

US3762161

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 11:14:36

Please record your **TEMPERATURE** in °F

| Audit                                                                                                                                                                                                                                                                              | User   | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-02T02:29:26', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: 'bcb0731d-8b3c-4ab4-8264-f1b625a93aea' User entered '96.5' | System | 02 Oct 2020 06:29:37 |

US3762161

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 11:14:36

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

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-02T02:29:31', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: 'bcb0731d-8b3c-4ab4-8264-f1b625a93aea' | System | 02 Oct 2020 06:29:37 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 02 Oct 2020 06:29:37 |

**US3762161**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 26 Nov 2020 11:14:36**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                                                           | User   | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-02T02:29:35', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: 'bcb0731d-8b3c-4ab4-8264-f1b625a93aea' User entered '02 Oct 2020 02:29' | System | 02 Oct 2020 06:29:37 |
|                                                                                                                                                                                                                                                                                                 | System | 02 Oct 2020 06:29:37 |

US3762161

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 26 Nov 2020 11:14:36**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '01 Oct 2020 12:00' | System | 30 Sep 2020 20:25:41 |



US3762161

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 26 Nov 2020 11:14:36**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '02 Oct 2020 11:59' | System | 30 Sep 2020 20:25:41 |

**US3762161**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 26 Nov 2020 11:14:36**

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 30 Sep 2020 20:25:41 |
| User entered 'Day 3' | System | 30 Sep 2020 20:25:41 |

US3762161

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 26 Nov 2020 11:14:36

Was **TEMPERATURE** taken?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-02T22:53:46', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: 'c7592f26-de2a-4544-b074-a29fed9c70a5' | System | 03 Oct 2020 02:54:17 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                                         | System | 03 Oct 2020 02:54:17 |

US3762161

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 26 Nov 2020 11:14:36

Please record your **TEMPERATURE** in °F

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-02T22:54:06', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: 'c7592f26-de2a-4544-b074-a29fed9c70a5' | System | 03 Oct 2020 02:54:17 |
| User entered '97.5'                                                                                                                                                                                                                                            | System | 03 Oct 2020 02:54:17 |

US3762161

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 26 Nov 2020 11:14:36

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

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-02T22:54:11', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: 'c7592f26-de2a-4544-b074-a29fed9c70a5' | System | 03 Oct 2020 02:54:17 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 03 Oct 2020 02:54:17 |

**US3762161**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 26 Nov 2020 11:14:36**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                                                           | User   | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-02T22:54:15', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: 'c7592f26-de2a-4544-b074-a29fed9c70a5' User entered '02 Oct 2020 22:54' | System | 03 Oct 2020 02:54:17 |
|                                                                                                                                                                                                                                                                                                 | System | 03 Oct 2020 02:54:17 |

US3762161

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 26 Nov 2020 11:14:36**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '02 Oct 2020 12:00' | System | 30 Sep 2020 20:25:41 |

US3762161

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 26 Nov 2020 11:14:36**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '03 Oct 2020 11:59' | System | 30 Sep 2020 20:25:41 |



US3762161

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 11:14:36

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 30 Sep 2020 20:25:41 |
| User entered 'Day 4' | System | 30 Sep 2020 20:25:41 |

US3762161

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 11:14:36

Was **TEMPERATURE** taken?

| Audit                                                                                                                                                                                                                                                                                 | User   | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-03T23:07:06', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: 'cd6c06f6-3d1d-4482-a50b-fd4e6b434d2e' User entered 'Yes (Y)' | System | 04 Oct 2020 03:07:22 |
|                                                                                                                                                                                                                                                                                       | System | 04 Oct 2020 03:07:22 |

US3762161

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 11:14:36

Please record your **TEMPERATURE** in °F

| Audit                                                                                                                                                                                                                                                                              | User   | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-03T23:07:12', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: 'cd6c06f6-3d1d-4482-a50b-fd4e6b434d2e' User entered '97.3' | System | 04 Oct 2020 03:07:22 |

US3762161

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 11:14:36

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

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-03T23:07:17', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: 'cd6c06f6-3d1d-4482-a50b-fd4e6b434d2e' | System | 04 Oct 2020 03:07:22 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 04 Oct 2020 03:07:22 |

US3762161

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 11:14:36

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                                                           | User   | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-03T23:07:20', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: 'cd6c06f6-3d1d-4482-a50b-fd4e6b434d2e' User entered '03 Oct 2020 23:07' | System | 04 Oct 2020 03:07:22 |
|                                                                                                                                                                                                                                                                                                 | System | 04 Oct 2020 03:07:22 |

US3762161

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 11:14:36

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '03 Oct 2020 12:00' | System | 30 Sep 2020 20:25:41 |

US3762161

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 26 Nov 2020 11:14:36**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '04 Oct 2020 11:59' | System | 30 Sep 2020 20:25:41 |

US3762161

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 26 Nov 2020 11:14:36

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 30 Sep 2020 20:25:41 |
| User entered 'Day 5' | System | 30 Sep 2020 20:25:41 |



US3762161

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 26 Nov 2020 11:14:36

Was **TEMPERATURE** taken?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-04T21:16:51', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '848096ca-d168-4c5f-b7c6-4638d8ecfe37' | System | 05 Oct 2020 01:16:57 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                                         | System | 05 Oct 2020 01:16:57 |

US3762161

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 26 Nov 2020 11:14:36

Please record your **TEMPERATURE** in °F

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-04T21:16:42', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '848096ca-d168-4c5f-b7c6-4638d8ecfe37' | System | 05 Oct 2020 01:16:57 |
| User entered '96.8'                                                                                                                                                                                                                                            | System | 05 Oct 2020 01:16:57 |

US3762161

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 26 Nov 2020 11:14:36

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

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-04T21:16:47', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '848096ca-d168-4c5f-b7c6-4638d8ecfe37' | System | 05 Oct 2020 01:16:57 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 05 Oct 2020 01:16:57 |

US3762161

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 26 Nov 2020 11:14:36

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-04T21:16:53', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '848096ca-d168-4c5f-b7c6-4638d8ecfe37' | System | 05 Oct 2020 01:16:57 |
| User entered '04 Oct 2020 21:16'                                                                                                                                                                                                                               | System | 05 Oct 2020 01:16:57 |

US3762161

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 26 Nov 2020 11:14:36**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '04 Oct 2020 12:00' | System | 30 Sep 2020 20:25:41 |

US3762161

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 26 Nov 2020 11:14:36**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '05 Oct 2020 11:59' | System | 30 Sep 2020 20:25:41 |

US3762161

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 26 Nov 2020 11:14:36

[TIMEPOINT](#)

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 30 Sep 2020 20:25:41 |
| User entered 'Day 6' | System | 30 Sep 2020 20:25:41 |

US3762161

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 26 Nov 2020 11:14:36

Was **TEMPERATURE** taken?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-06T09:43:38', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '891beeb0-e28b-4ced-bd53-d3cd2440a443' | System | 06 Oct 2020 13:43:55 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                                         | System | 06 Oct 2020 13:43:55 |



US3762161

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 26 Nov 2020 11:14:36

Please record your **TEMPERATURE** in °F

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-06T09:43:49', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '891beeb0-e28b-4ced-bd53-d3cd2440a443' | System | 06 Oct 2020 13:43:55 |
| User entered '96.5'                                                                                                                                                                                                                                            | System | 06 Oct 2020 13:43:55 |

US3762161

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 26 Nov 2020 11:14:36

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

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-06T09:43:14', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '891beeb0-e28b-4ced-bd53-d3cd2440a443' | System | 06 Oct 2020 13:43:55 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 06 Oct 2020 13:43:55 |

**US3762161**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 26 Nov 2020 11:14:36**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                                                           | User   | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-06T09:43:54', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '891beeb0-e28b-4ced-bd53-d3cd2440a443' User entered '06 Oct 2020 09:43' | System | 06 Oct 2020 13:43:55 |
|                                                                                                                                                                                                                                                                                                 | System | 06 Oct 2020 13:43:55 |

US3762161

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 26 Nov 2020 11:14:36**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '05 Oct 2020 12:00' | System | 30 Sep 2020 20:25:41 |

US3762161

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 26 Nov 2020 11:14:36**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '06 Oct 2020 11:59' | System | 30 Sep 2020 20:25:41 |

US3762161

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 26 Nov 2020 11:14:36

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 30 Sep 2020 20:25:41 |
| User entered 'Day 7' | System | 30 Sep 2020 20:25:41 |

US3762161

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 26 Nov 2020 11:14:36

Was **TEMPERATURE** taken?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-06T21:30:22', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: 'f6c5f442-5f71-43a6-a3f7-b894e3163971' | System | 07 Oct 2020 01:30:41 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                                         | System | 07 Oct 2020 01:30:41 |

US3762161

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 26 Nov 2020 11:14:36

Please record your **TEMPERATURE** in °F

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-06T21:30:26', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: 'f6c5f442-5f71-43a6-a3f7-b894e3163971' | System | 07 Oct 2020 01:30:41 |
| User entered '96.5'                                                                                                                                                                                                                                            | System | 07 Oct 2020 01:30:41 |



US3762161

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 26 Nov 2020 11:14:36

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

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-06T21:30:33', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: 'f6c5f442-5f71-43a6-a3f7-b894e3163971' | System | 07 Oct 2020 01:30:41 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 07 Oct 2020 01:30:41 |

US3762161

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 26 Nov 2020 11:14:36

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                                                           | User   | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-06T21:30:36', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: 'f6c5f442-5f71-43a6-a3f7-b894e3163971' User entered '06 Oct 2020 21:30' | System | 07 Oct 2020 01:30:41 |
|                                                                                                                                                                                                                                                                                                 | System | 07 Oct 2020 01:30:41 |

US3762161

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 26 Nov 2020 11:14:36**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '06 Oct 2020 12:00' | System | 30 Sep 2020 20:25:41 |

US3762161

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 26 Nov 2020 11:14:36**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '07 Oct 2020 11:59' | System | 30 Sep 2020 20:25:41 |

**US3762161**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 11:14:36**

**TIMEPOINT**

| Audit                                                                | User   | Time (GMT)           |
|----------------------------------------------------------------------|--------|----------------------|
| Data entry locked.                                                   | System | 30 Sep 2020 20:25:41 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 30 Sep 2020 20:25:41 |

US3762161

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 11:14:36

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 (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-30T16:27:21', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: 'bc0987fd-1dfb-4a93-95dd-58a88b4d1e41' | System | 30 Sep 2020 20:27:53 |
| User entered 'None (1)'                                                                                                                                                                                                                                        | System | 30 Sep 2020 20:27:53 |

US3762161

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 11:14:36

Is there any REDNESS AT INJECTION SITE?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-30T16:27:25', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: 'bc0987fd-1dfb-4a93-95dd-58a88b4d1e41' | System | 30 Sep 2020 20:27:53 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 30 Sep 2020 20:27:53 |

US3762161

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 11:14:36

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

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-30T16:27:29', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: 'bc0987fd-1dfb-4a93-95dd-58a88b4d1e41' | System | 30 Sep 2020 20:27:53 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 30 Sep 2020 20:27:53 |



US3762161

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 11:14:36

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 (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-30T16:27:47', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: 'bc0987fd-1dfb-4a93-95dd-58a88b4d1e41' | System | 30 Sep 2020 20:27:53 |
| User entered 'None (1)'                                                                                                                                                                                                                                        | System | 30 Sep 2020 20:27:53 |

**US3762161**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 11:14:36**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-30T16:27:51', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: 'bc0987fd-1dfb-4a93-95dd-58a88b4d1e41' | System | 30 Sep 2020 20:27:53 |
| User entered '30 Sep 2020 16:27'                                                                                                                                                                                                                               | System | 30 Sep 2020 20:27:53 |

US3762161

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 11:14:36**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '30 Sep 2020 15:50' | System | 30 Sep 2020 20:25:41 |

US3762161

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 11:14:36**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '30 Sep 2020 18:20' | System | 30 Sep 2020 20:25:41 |

US3762161

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 26 Nov 2020 11:14:36

**TIMEPOINT**

| Audit                                             | User   | Time (GMT)           |
|---------------------------------------------------|--------|----------------------|
| Data entry locked.                                | System | 30 Sep 2020 20:25:41 |
| User entered 'Day 1, after vaccination (at home)' | System | 30 Sep 2020 20:25:41 |

US3762161

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 26 Nov 2020 11:14:36

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 (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-30T23:04:58', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: 'c15bce23-8e2a-452f-8f02-467e296b0d07' | System | 01 Oct 2020 03:05:16 |
| User entered 'None (1)'                                                                                                                                                                                                                                        | System | 01 Oct 2020 03:05:16 |

US3762161

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 26 Nov 2020 11:14:36

Is there any REDNESS AT INJECTION SITE?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-30T23:05:01', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: 'c15bce23-8e2a-452f-8f02-467e296b0d07' | System | 01 Oct 2020 03:05:16 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 01 Oct 2020 03:05:16 |

US3762161

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 26 Nov 2020 11:14:36

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

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-30T23:05:05', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: 'c15bce23-8e2a-452f-8f02-467e296b0d07' | System | 01 Oct 2020 03:05:16 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 01 Oct 2020 03:05:16 |



US3762161

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 26 Nov 2020 11:14:36

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 (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-30T23:05:09', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: 'c15bce23-8e2a-452f-8f02-467e296b0d07' | System | 01 Oct 2020 03:05:16 |
| User entered 'None (1)'                                                                                                                                                                                                                                        | System | 01 Oct 2020 03:05:16 |

**US3762161**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 11:14:36**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-30T23:05:12', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: 'c15bce23-8e2a-452f-8f02-467e296b0d07' | System | 01 Oct 2020 03:05:16 |
| User entered '30 Sep 2020 23:05'                                                                                                                                                                                                                               | System | 01 Oct 2020 03:05:16 |

US3762161

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 11:14:36**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '30 Sep 2020 19:15' | System | 30 Sep 2020 20:25:41 |

US3762161

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 11:14:36**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '01 Oct 2020 11:59' | System | 30 Sep 2020 20:25:41 |

US3762161

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 26 Nov 2020 11:14:36

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 30 Sep 2020 20:25:41 |
| User entered 'Day 2' | System | 30 Sep 2020 20:25:41 |

US3762161

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 26 Nov 2020 11:14:36

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 (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-02T02:29:55', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: 'c1ac1eab-94fd-41dc-94b2-f19b0bce6228' | System | 02 Oct 2020 06:30:15 |
| User entered 'None (1)'                                                                                                                                                                                                                                        | System | 02 Oct 2020 06:30:15 |

US3762161

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 26 Nov 2020 11:14:36

Is there any REDNESS AT INJECTION SITE?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-02T02:30:00', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: 'c1ac1eab-94fd-41dc-94b2-f19b0bce6228' | System | 02 Oct 2020 06:30:15 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 02 Oct 2020 06:30:15 |

US3762161

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 26 Nov 2020 11:14:36

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

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-02T02:30:04', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: 'c1ac1eab-94fd-41dc-94b2-f19b0bce6228' | System | 02 Oct 2020 06:30:15 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 02 Oct 2020 06:30:15 |



US3762161

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 26 Nov 2020 11:14:36

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 (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-02T02:30:09', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: 'c1ac1eab-94fd-41dc-94b2-f19b0bce6228' | System | 02 Oct 2020 06:30:15 |
| User entered 'None (1)'                                                                                                                                                                                                                                        | System | 02 Oct 2020 06:30:15 |

US3762161

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 26 Nov 2020 11:14:36

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-02T02:30:12', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: 'c1ac1eab-94fd-41dc-94b2-f19b0bce6228' | System | 02 Oct 2020 06:30:15 |
| User entered '02 Oct 2020 02:30'                                                                                                                                                                                                                               | System | 02 Oct 2020 06:30:15 |

US3762161

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 11:14:36**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '01 Oct 2020 12:00' | System | 30 Sep 2020 20:25:41 |

US3762161

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 11:14:36**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '02 Oct 2020 11:59' | System | 30 Sep 2020 20:25:41 |

**US3762161**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 11:14:36**

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 30 Sep 2020 20:25:41 |
| User entered 'Day 3' | System | 30 Sep 2020 20:25:41 |

US3762161

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 26 Nov 2020 11:14:36

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 (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-02T22:54:29', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '51643f69-c818-4b7c-bc05-3b84e775094a' | System | 03 Oct 2020 02:59:09 |
| User entered 'None (1)'                                                                                                                                                                                                                                        | System | 03 Oct 2020 02:59:09 |

US3762161

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 26 Nov 2020 11:14:36

Is there any REDNESS AT INJECTION SITE?

| Audit                                                                                                                                                                                                                                                                                 | User   | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-02T22:54:34', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '51643f69-c818-4b7c-bc05-3b84e775094a' User entered 'Yes (Y)' | System | 03 Oct 2020 02:59:09 |

US3762161

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 26 Nov 2020 11:14:36

Please record - REDNESS AT INJECTION SITE (in mm)

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

| Audit                                                                                                                                                                                                                                                                           | User   | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-02T22:58:26', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '51643f69-c818-4b7c-bc05-3b84e775094a' User entered '7' | System | 03 Oct 2020 02:59:09 |
|                                                                                                                                                                                                                                                                                 | System | 03 Oct 2020 02:59:09 |



US3762161

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 26 Nov 2020 11:14:36

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

| Audit                                                                                                                                                                                                                                                                                 | User   | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-02T22:58:32', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '51643f69-c818-4b7c-bc05-3b84e775094a' User entered 'Yes (Y)' | System | 03 Oct 2020 02:59:09 |

US3762161

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 26 Nov 2020 11:14:36

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 (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-02T22:58:54', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '51643f69-c818-4b7c-bc05-3b84e775094a' User entered '3' | System | 03 Oct 2020 02:59:09 |
|                                                                                                                                                                                                                                                                                 | System | 03 Oct 2020 02:59:09 |

US3762161

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 26 Nov 2020 11:14:36

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 (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-02T22:59:00', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '51643f69-c818-4b7c-bc05-3b84e775094a' | System | 03 Oct 2020 02:59:09 |
| User entered 'None (1)'                                                                                                                                                                                                                                        | System | 03 Oct 2020 02:59:09 |

**US3762161**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 11:14:36**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-02T22:59:04', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '51643f69-c818-4b7c-bc05-3b84e775094a' | System | 03 Oct 2020 02:59:09 |
| User entered '02 Oct 2020 22:59'                                                                                                                                                                                                                               | System | 03 Oct 2020 02:59:09 |

US3762161

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 11:14:36**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '02 Oct 2020 12:00' | System | 30 Sep 2020 20:25:41 |

US3762161

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 11:14:36**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '03 Oct 2020 11:59' | System | 30 Sep 2020 20:25:41 |

US3762161

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 26 Nov 2020 11:14:36

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 30 Sep 2020 20:25:41 |
| User entered 'Day 4' | System | 30 Sep 2020 20:25:41 |

US3762161

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 26 Nov 2020 11:14:36

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 (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-03T23:07:26', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '5cc01959-ab0c-4d93-b178-1d67375c9aaa' | System | 04 Oct 2020 03:08:06 |
| User entered 'None (1)'                                                                                                                                                                                                                                        | System | 04 Oct 2020 03:08:06 |



US3762161

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 26 Nov 2020 11:14:36

Is there any REDNESS AT INJECTION SITE?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-03T23:07:36', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '5cc01959-ab0c-4d93-b178-1d67375c9aaa' | System | 04 Oct 2020 03:08:06 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 04 Oct 2020 03:08:06 |

US3762161

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 26 Nov 2020 11:14:36

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

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-03T23:07:44', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '5cc01959-ab0c-4d93-b178-1d67375c9aaa' | System | 04 Oct 2020 03:08:06 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                                         | System | 04 Oct 2020 03:08:06 |

US3762161

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 26 Nov 2020 11:14:36

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 (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-03T23:07:58', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '5cc01959-ab0c-4d93-b178-1d67375c9aaa' User entered '3' | System | 04 Oct 2020 03:08:06 |
|                                                                                                                                                                                                                                                                                 | System | 04 Oct 2020 03:08:06 |

US3762161

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 26 Nov 2020 11:14:36

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 (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-03T23:08:01', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '5cc01959-ab0c-4d93-b178-1d67375c9aaa' | System | 04 Oct 2020 03:08:06 |
| User entered 'None (1)'                                                                                                                                                                                                                                        | System | 04 Oct 2020 03:08:06 |

US3762161

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 26 Nov 2020 11:14:36

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-03T23:08:04', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '5cc01959-ab0c-4d93-b178-1d67375c9aaa' | System | 04 Oct 2020 03:08:06 |
| User entered '03 Oct 2020 23:08'                                                                                                                                                                                                                               | System | 04 Oct 2020 03:08:06 |

US3762161

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 11:14:36**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '03 Oct 2020 12:00' | System | 30 Sep 2020 20:25:41 |

US3762161

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 11:14:36**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '04 Oct 2020 11:59' | System | 30 Sep 2020 20:25:41 |

**US3762161**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 11:14:36**

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 30 Sep 2020 20:25:41 |
| User entered 'Day 5' | System | 30 Sep 2020 20:25:41 |



US3762161

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 26 Nov 2020 11:14:36

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 (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-04T21:16:58', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: 'c5d36cd0-48c0-43df-bf1c-bcaf2044fa61' | System | 05 Oct 2020 01:17:14 |
| User entered 'None (1)'                                                                                                                                                                                                                                        | System | 05 Oct 2020 01:17:14 |

US3762161

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 26 Nov 2020 11:14:36

Is there any REDNESS AT INJECTION SITE?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-04T21:17:01', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: 'c5d36cd0-48c0-43df-bf1c-bcaf2044fa61' | System | 05 Oct 2020 01:17:14 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 05 Oct 2020 01:17:14 |

US3762161

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 26 Nov 2020 11:14:36

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

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-04T21:17:05', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: 'c5d36cd0-48c0-43df-bf1c-bcaf2044fa61' | System | 05 Oct 2020 01:17:14 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 05 Oct 2020 01:17:14 |

US3762161

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 26 Nov 2020 11:14:36

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 (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-04T21:17:09', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: 'c5d36cd0-48c0-43df-bf1c-bcaf2044fa61' | System | 05 Oct 2020 01:17:14 |
| User entered 'None (1)'                                                                                                                                                                                                                                        | System | 05 Oct 2020 01:17:14 |

**US3762161**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 11:14:36**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-04T21:17:12', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: 'c5d36cd0-48c0-43df-bf1c-bcaf2044fa61' | System | 05 Oct 2020 01:17:14 |
| User entered '04 Oct 2020 21:17'                                                                                                                                                                                                                               | System | 05 Oct 2020 01:17:14 |

US3762161

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 11:14:36**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '04 Oct 2020 12:00' | System | 30 Sep 2020 20:25:41 |

US3762161

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 11:14:36**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '05 Oct 2020 11:59' | System | 30 Sep 2020 20:25:41 |

US3762161

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 26 Nov 2020 11:14:36

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 30 Sep 2020 20:25:41 |
| User entered 'Day 6' | System | 30 Sep 2020 20:25:41 |



US3762161

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 26 Nov 2020 11:14:36

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 (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-06T09:43:59', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '81459ae7-a4ae-47ed-8522-e54f6c83bff0' | System | 06 Oct 2020 13:44:18 |
| User entered 'None (1)'                                                                                                                                                                                                                                        | System | 06 Oct 2020 13:44:18 |

US3762161

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 26 Nov 2020 11:14:36

Is there any REDNESS AT INJECTION SITE?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-06T09:44:03', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '81459ae7-a4ae-47ed-8522-e54f6c83bff0' | System | 06 Oct 2020 13:44:18 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 06 Oct 2020 13:44:18 |

US3762161

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 26 Nov 2020 11:14:36

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

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-06T09:44:07', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '81459ae7-a4ae-47ed-8522-e54f6c83bff0' | System | 06 Oct 2020 13:44:18 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 06 Oct 2020 13:44:18 |

US3762161

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 26 Nov 2020 11:14:36

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 (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-06T09:44:11', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '81459ae7-a4ae-47ed-8522-e54f6c83bff0' | System | 06 Oct 2020 13:44:18 |
| User entered 'None (1)'                                                                                                                                                                                                                                        | System | 06 Oct 2020 13:44:18 |

US3762161

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 26 Nov 2020 11:14:36

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-06T09:44:14', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '81459ae7-a4ae-47ed-8522-e54f6c83bff0' | System | 06 Oct 2020 13:44:18 |
| User entered '06 Oct 2020 09:44'                                                                                                                                                                                                                               | System | 06 Oct 2020 13:44:18 |

US3762161

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 11:14:36**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '05 Oct 2020 12:00' | System | 30 Sep 2020 20:25:41 |

US3762161

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 11:14:36**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '06 Oct 2020 11:59' | System | 30 Sep 2020 20:25:41 |

**US3762161**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 11:14:36**

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 30 Sep 2020 20:25:41 |
| User entered 'Day 7' | System | 30 Sep 2020 20:25:41 |



US3762161

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 26 Nov 2020 11:14:36

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 (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-06T21:30:41', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '33bb6b24-dfc1-4fc1-9e63-1f6afe800813' | System | 07 Oct 2020 01:30:57 |
| User entered 'None (1)'                                                                                                                                                                                                                                        | System | 07 Oct 2020 01:30:57 |

US3762161

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 26 Nov 2020 11:14:36

Is there any REDNESS AT INJECTION SITE?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-06T21:30:44', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '33bb6b24-dfc1-4fc1-9e63-1f6afe800813' | System | 07 Oct 2020 01:30:57 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 07 Oct 2020 01:30:57 |

US3762161

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 26 Nov 2020 11:14:36

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

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-06T21:30:47', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '33bb6b24-dfc1-4fc1-9e63-1f6afe800813' | System | 07 Oct 2020 01:30:57 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 07 Oct 2020 01:30:57 |

US3762161

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 26 Nov 2020 11:14:36

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 (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-06T21:30:50', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '33bb6b24-dfc1-4fc1-9e63-1f6afe800813' | System | 07 Oct 2020 01:30:57 |
| User entered 'None (1)'                                                                                                                                                                                                                                        | System | 07 Oct 2020 01:30:57 |

**US3762161**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 11:14:36**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-06T21:30:53', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '33bb6b24-dfc1-4fc1-9e63-1f6afe800813' | System | 07 Oct 2020 01:30:57 |
| User entered '06 Oct 2020 21:30'                                                                                                                                                                                                                               | System | 07 Oct 2020 01:30:57 |

US3762161

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 11:14:36**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '06 Oct 2020 12:00' | System | 30 Sep 2020 20:25:41 |

US3762161

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 11:14:36**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '07 Oct 2020 11:59' | System | 30 Sep 2020 20:25:41 |

**US3762161**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 11:14:36**

**TIMEPOINT**

| Audit                                                                | User   | Time (GMT)           |
|----------------------------------------------------------------------|--------|----------------------|
| Data entry locked.                                                   | System | 30 Sep 2020 20:25:41 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 30 Sep 2020 20:25:41 |



US3762161

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 11:14:36

**HEADACHE**

| Audit                                                                                                                                                                                                                                                         | User   | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-30T16:28:05', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '5a9e9049-add3-46c9-a954-f5ef41aee1b' | System | 30 Sep 2020 20:28:42 |
| User entered 'None (0)'                                                                                                                                                                                                                                       | System | 30 Sep 2020 20:28:42 |

US3762161

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 11:14:36

**FATIGUE**

| Audit                                                                                                                                                                                                                                                                                 | User   | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-30T16:28:09', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '5a9e9049-add3-46c9-a954-f5ef41aee1b' User entered 'None (0)' | System | 30 Sep 2020 20:28:42 |
|                                                                                                                                                                                                                                                                                       | System | 30 Sep 2020 20:28:42 |

US3762161

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 11:14:36

**MUSCLE ACHES ALL OVER BODY**

| Audit                                                                                                                                                                                                                                                         | User   | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-30T16:28:15', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '5a9e9049-add3-46c9-a954-f5ef41aee1b' | System | 30 Sep 2020 20:28:42 |
| User entered 'None (0)'                                                                                                                                                                                                                                       | System | 30 Sep 2020 20:28:42 |

US3762161

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 11:14:36

**JOINT ACHES IN SEVERAL JOINTS**

| Audit                                                                                                                                                                                                                                                         | User   | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-30T16:28:18', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '5a9e9049-add3-46c9-a954-f5ef41aee1b' | System | 30 Sep 2020 20:28:42 |
| User entered 'None (0)'                                                                                                                                                                                                                                       | System | 30 Sep 2020 20:28:42 |

US3762161

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 11:14:36

**NAUSEA/VOMITING**

| Audit                                                                                                                                                                                                                                                         | User   | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-30T16:28:22', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '5a9e9049-add3-46c9-a954-f5ef41aee1b' | System | 30 Sep 2020 20:28:42 |
| User entered 'None (0)'                                                                                                                                                                                                                                       | System | 30 Sep 2020 20:28:42 |

US3762161

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 11:14:36

**CHILLS**

| Audit                                                                                                                                                                                                                                                         | User   | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-30T16:28:27', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '5a9e9049-add3-46c9-a954-f5ef41aee1b' | System | 30 Sep 2020 20:28:42 |
| User entered 'None (0)'                                                                                                                                                                                                                                       | System | 30 Sep 2020 20:28:42 |

US3762161

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 11:14:36

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 (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-30T16:28:34', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '5a9e9049-add3-46c9-a954-f5ef41aee1b' User entered 'No (N)' | System | 30 Sep 2020 20:28:42 |

**US3762161**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 11:14:36**

[PC Time stamp](#)

| Audit                                                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-30T16:28:37', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '5a9e9049-add3-46c9-a954-f5ef41aee1b' User entered '30 Sep 2020 16:28' | System | 30 Sep 2020 20:28:42 |
|                                                                                                                                                                                                                                                                                                | System | 30 Sep 2020 20:28:42 |



US3762161

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 11:14:36

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '30 Sep 2020 15:50' | System | 30 Sep 2020 20:25:41 |

US3762161

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 11:14:36**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '30 Sep 2020 18:20' | System | 30 Sep 2020 20:25:41 |

US3762161

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 11:14:36

**TIMEPOINT**

| Audit                                             | User   | Time (GMT)           |
|---------------------------------------------------|--------|----------------------|
| Data entry locked.                                | System | 30 Sep 2020 20:25:41 |
| User entered 'Day 1, after vaccination (at home)' | System | 30 Sep 2020 20:25:41 |

US3762161

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 11:14:36

**HEADACHE**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-30T23:05:17', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '1cee65bd-7466-4653-832d-45b3db71a3e2' | System | 01 Oct 2020 03:05:40 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 01 Oct 2020 03:05:40 |

US3762161

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 11:14:36

**FATIGUE**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-30T23:05:20', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '1cee65bd-7466-4653-832d-45b3db71a3e2' | System | 01 Oct 2020 03:05:40 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 01 Oct 2020 03:05:40 |

US3762161

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 11:14:36

**MUSCLE ACHES ALL OVER BODY**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-30T23:05:23', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '1cee65bd-7466-4653-832d-45b3db71a3e2' | System | 01 Oct 2020 03:05:40 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 01 Oct 2020 03:05:40 |

US3762161

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 11:14:36

**JOINT ACHES IN SEVERAL JOINTS**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-30T23:05:25', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '1cee65bd-7466-4653-832d-45b3db71a3e2' | System | 01 Oct 2020 03:05:40 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 01 Oct 2020 03:05:40 |

US3762161

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 11:14:36

**NAUSEA/VOMITING**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-30T23:05:29', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '1cee65bd-7466-4653-832d-45b3db71a3e2' | System | 01 Oct 2020 03:05:40 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 01 Oct 2020 03:05:40 |



US3762161

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 11:14:36

**CHILLS**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-30T23:05:32', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '1cee65bd-7466-4653-832d-45b3db71a3e2' | System | 01 Oct 2020 03:05:40 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 01 Oct 2020 03:05:40 |

US3762161

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 11:14:36

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 (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-30T23:05:36', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '1cee65bd-7466-4653-832d-45b3db71a3e2' | System | 01 Oct 2020 03:05:40 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 01 Oct 2020 03:05:40 |

**US3762161**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 11:14:36**

[PC Time stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-30T23:05:38', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '1cee65bd-7466-4653-832d-45b3db71a3e2' | System | 01 Oct 2020 03:05:40 |
| User entered '30 Sep 2020 23:05'                                                                                                                                                                                                                               | System | 01 Oct 2020 03:05:40 |

US3762161

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 11:14:36

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '30 Sep 2020 19:15' | System | 30 Sep 2020 20:25:41 |

US3762161

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 11:14:36

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '01 Oct 2020 11:59' | System | 30 Sep 2020 20:25:41 |

**US3762161**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 11:14:36**

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 30 Sep 2020 20:25:41 |
| User entered 'Day 2' | System | 30 Sep 2020 20:25:41 |

US3762161

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 11:14:36

**HEADACHE**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-02T02:30:21', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: 'b1842b1a-89af-46ff-b412-cd01063cb727' | System | 02 Oct 2020 06:31:09 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 02 Oct 2020 06:31:09 |

US3762161

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 11:14:36

**FATIGUE**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-02T02:30:27', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: 'b1842b1a-89af-46ff-b412-cd01063cb727' | System | 02 Oct 2020 06:31:09 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 02 Oct 2020 06:31:09 |



US3762161

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 11:14:36

**MUSCLE ACHES ALL OVER BODY**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-02T02:30:32', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: 'b1842b1a-89af-46ff-b412-cd01063cb727' | System | 02 Oct 2020 06:31:09 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 02 Oct 2020 06:31:09 |

US3762161

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 11:14:36

**JOINT ACHES IN SEVERAL JOINTS**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-02T02:30:38', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: 'b1842b1a-89af-46ff-b412-cd01063cb727' | System | 02 Oct 2020 06:31:09 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 02 Oct 2020 06:31:09 |

**US3762161**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 11:14:36**

**NAUSEA/VOMITING**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-02T02:30:42', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: 'b1842b1a-89af-46ff-b412-cd01063cb727' | System | 02 Oct 2020 06:31:09 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 02 Oct 2020 06:31:09 |

US3762161

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 11:14:36

CHILLS

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-02T02:30:45', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: 'b1842b1a-89af-46ff-b412-cd01063cb727' | System | 02 Oct 2020 06:31:09 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 02 Oct 2020 06:31:09 |

US3762161

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 11:14:36

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 (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-02T02:31:02', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: 'b1842b1a-89af-46ff-b412-cd01063cb727' | System | 02 Oct 2020 06:31:09 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 02 Oct 2020 06:31:09 |

**US3762161**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 11:14:36**

[PC Time stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-02T02:31:05', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: 'b1842b1a-89af-46ff-b412-cd01063cb727' | System | 02 Oct 2020 06:31:09 |
| User entered '02 Oct 2020 02:31'                                                                                                                                                                                                                               | System | 02 Oct 2020 06:31:09 |

US3762161

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 11:14:36

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '01 Oct 2020 12:00' | System | 30 Sep 2020 20:25:41 |

US3762161

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 11:14:36**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '02 Oct 2020 11:59' | System | 30 Sep 2020 20:25:41 |



US3762161

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 11:14:36

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 30 Sep 2020 20:25:41 |
| User entered 'Day 3' | System | 30 Sep 2020 20:25:41 |

US3762161

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 11:14:36

**HEADACHE**

| Audit                                                                                                                                                                                                                                                                                  | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-02T22:59:10', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '668a5470-4576-4ce0-af70-47495ee6561f' User entered 'None (0)' | System | 03 Oct 2020 02:59:37 |
|                                                                                                                                                                                                                                                                                        | System | 03 Oct 2020 02:59:37 |

US3762161

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 11:14:36

**FATIGUE**

| Audit                                                                                                                                                                                                                                                                                  | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-02T22:59:14', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '668a5470-4576-4ce0-af70-47495ee6561f' User entered 'None (0)' | System | 03 Oct 2020 02:59:37 |
|                                                                                                                                                                                                                                                                                        | System | 03 Oct 2020 02:59:37 |

US3762161

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 11:14:36

**MUSCLE ACHES ALL OVER BODY**

| Audit                                                                                                                                                                                                                                                                                  | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-02T22:59:17', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '668a5470-4576-4ce0-af70-47495ee6561f' User entered 'None (0)' | System | 03 Oct 2020 02:59:37 |
|                                                                                                                                                                                                                                                                                        | System | 03 Oct 2020 02:59:37 |

US3762161

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 11:14:36

**JOINT ACHES IN SEVERAL JOINTS**

| Audit                                                                                                                                                                                                                                                                                  | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-02T22:59:20', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '668a5470-4576-4ce0-af70-47495ee6561f' User entered 'None (0)' | System | 03 Oct 2020 02:59:37 |

US3762161

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 11:14:36

**NAUSEA/VOMITING**

| Audit                                                                                                                                                                                                                                                                                  | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-02T22:59:23', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '668a5470-4576-4ce0-af70-47495ee6561f' User entered 'None (0)' | System | 03 Oct 2020 02:59:37 |
|                                                                                                                                                                                                                                                                                        | System | 03 Oct 2020 02:59:37 |

US3762161

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 11:14:36

**CHILLS**

| Audit                                                                                                                                                                                                                                                                                  | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-02T22:59:26', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '668a5470-4576-4ce0-af70-47495ee6561f' User entered 'None (0)' | System | 03 Oct 2020 02:59:37 |
|                                                                                                                                                                                                                                                                                        | System | 03 Oct 2020 02:59:37 |

US3762161

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 11:14:36

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 (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-02T22:59:32', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '668a5470-4576-4ce0-af70-47495ee6561f' User entered 'No (N)' | System | 03 Oct 2020 02:59:37 |



**US3762161**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 11:14:36**

[PC Time stamp](#)

| Audit                                                                                                                                                                                                                                                                                           | User   | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-02T22:59:35', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '668a5470-4576-4ce0-af70-47495ee6561f' User entered '02 Oct 2020 22:59' | System | 03 Oct 2020 02:59:37 |

US3762161

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 11:14:36

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '02 Oct 2020 12:00' | System | 30 Sep 2020 20:25:41 |

US3762161

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 11:14:36

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '03 Oct 2020 11:59' | System | 30 Sep 2020 20:25:41 |

**US3762161**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 11:14:36**

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 30 Sep 2020 20:25:41 |
| User entered 'Day 4' | System | 30 Sep 2020 20:25:41 |

**US3762161**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 11:14:36**

**HEADACHE**

| Audit                                                                                                                                                                                                                                                                                  | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-03T23:08:09', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '7e7a9bfc-9782-4dd8-8f1c-87b827a31b2e' User entered 'None (0)' | System | 04 Oct 2020 03:08:37 |
|                                                                                                                                                                                                                                                                                        | System | 04 Oct 2020 03:08:37 |

US3762161

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 11:14:36

**FATIGUE**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-03T23:08:12', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '7e7a9bfc-9782-4dd8-8f1c-87b827a31b2e' | System | 04 Oct 2020 03:08:37 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 04 Oct 2020 03:08:37 |

US3762161

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 11:14:36

**MUSCLE ACHES ALL OVER BODY**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-03T23:08:15', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '7e7a9bfc-9782-4dd8-8f1c-87b827a31b2e' | System | 04 Oct 2020 03:08:37 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 04 Oct 2020 03:08:37 |

US3762161

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 11:14:36

**JOINT ACHES IN SEVERAL JOINTS**

| Audit                                                                                                                                                                                                                                                                                  | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-03T23:08:18', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '7e7a9bfc-9782-4dd8-8f1c-87b827a31b2e' User entered 'None (0)' | System | 04 Oct 2020 03:08:37 |
|                                                                                                                                                                                                                                                                                        | System | 04 Oct 2020 03:08:37 |



US3762161

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 11:14:36

**NAUSEA/VOMITING**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-03T23:08:21', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '7e7a9bfc-9782-4dd8-8f1c-87b827a31b2e' | System | 04 Oct 2020 03:08:37 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 04 Oct 2020 03:08:37 |

US3762161

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 11:14:36

**CHILLS**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-03T23:08:24', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '7e7a9bfc-9782-4dd8-8f1c-87b827a31b2e' | System | 04 Oct 2020 03:08:37 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 04 Oct 2020 03:08:37 |

US3762161

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 11:14:36

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 (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-03T23:08:29', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '7e7a9bfc-9782-4dd8-8f1c-87b827a31b2e' | System | 04 Oct 2020 03:08:37 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 04 Oct 2020 03:08:37 |

**US3762161**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 11:14:36**

[PC Time stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-03T23:08:32', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '7e7a9bfc-9782-4dd8-8f1c-87b827a31b2e' | System | 04 Oct 2020 03:08:37 |
| User entered '03 Oct 2020 23:08'                                                                                                                                                                                                                               | System | 04 Oct 2020 03:08:37 |

US3762161

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 11:14:36

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '03 Oct 2020 12:00' | System | 30 Sep 2020 20:25:41 |

US3762161

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 11:14:36

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '04 Oct 2020 11:59' | System | 30 Sep 2020 20:25:41 |

**US3762161**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 11:14:36**

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 30 Sep 2020 20:25:41 |
| User entered 'Day 5' | System | 30 Sep 2020 20:25:41 |

US3762161

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 11:14:36

**HEADACHE**

| Audit                                                                                                                                                                                                                                                                                  | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-04T21:17:17', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '54ca638b-b66a-4396-bd12-47c36bf95c8e' User entered 'None (0)' | System | 05 Oct 2020 01:17:38 |
|                                                                                                                                                                                                                                                                                        | System | 05 Oct 2020 01:17:38 |



US3762161

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 11:14:36

**FATIGUE**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-04T21:17:20', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '54ca638b-b66a-4396-bd12-47c36bf95c8e' | System | 05 Oct 2020 01:17:38 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 05 Oct 2020 01:17:38 |

US3762161

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 11:14:36

**MUSCLE ACHES ALL OVER BODY**

| Audit                                                                                                                                                                                                                                                                                  | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-04T21:17:23', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '54ca638b-b66a-4396-bd12-47c36bf95c8e' User entered 'None (0)' | System | 05 Oct 2020 01:17:38 |
|                                                                                                                                                                                                                                                                                        | System | 05 Oct 2020 01:17:38 |

US3762161

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 11:14:36

**JOINT ACHES IN SEVERAL JOINTS**

| Audit                                                                                                                                                                                                                                                                                  | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-04T21:17:25', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '54ca638b-b66a-4396-bd12-47c36bf95c8e' User entered 'None (0)' | System | 05 Oct 2020 01:17:38 |
|                                                                                                                                                                                                                                                                                        | System | 05 Oct 2020 01:17:38 |

US3762161

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 11:14:36

**NAUSEA/VOMITING**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-04T21:17:28', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '54ca638b-b66a-4396-bd12-47c36bf95c8e' | System | 05 Oct 2020 01:17:38 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 05 Oct 2020 01:17:38 |

US3762161

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 11:14:36

**CHILLS**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-04T21:17:31', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '54ca638b-b66a-4396-bd12-47c36bf95c8e' | System | 05 Oct 2020 01:17:38 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 05 Oct 2020 01:17:38 |

US3762161

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 11:14:36

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 (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-04T21:17:35', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '54ca638b-b66a-4396-bd12-47c36bf95c8e' | System | 05 Oct 2020 01:17:38 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 05 Oct 2020 01:17:38 |

**US3762161**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 11:14:36**

[PC Time stamp](#)

| Audit                                                                                                                                                                                                                                                                                           | User   | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-04T21:17:37', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '54ca638b-b66a-4396-bd12-47c36bf95c8e' User entered '04 Oct 2020 21:17' | System | 05 Oct 2020 01:17:38 |
|                                                                                                                                                                                                                                                                                                 | System | 05 Oct 2020 01:17:38 |

US3762161

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 11:14:36

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '04 Oct 2020 12:00' | System | 30 Sep 2020 20:25:41 |



US3762161

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 11:14:36

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '05 Oct 2020 11:59' | System | 30 Sep 2020 20:25:41 |

**US3762161**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 11:14:36**

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 30 Sep 2020 20:25:41 |
| User entered 'Day 6' | System | 30 Sep 2020 20:25:41 |

US3762161

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 11:14:36

**HEADACHE**

| Audit                                                                                                                                                                                                                                                                                  | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-06T09:44:22', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '26aa56fd-1d85-4c51-adc8-63e550a2621b' User entered 'None (0)' | System | 06 Oct 2020 13:44:52 |
|                                                                                                                                                                                                                                                                                        | System | 06 Oct 2020 13:44:52 |

US3762161

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 11:14:36

**FATIGUE**

| Audit                                                                                                                                                                                                                                                                                  | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-06T09:44:25', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '26aa56fd-1d85-4c51-adc8-63e550a2621b' User entered 'None (0)' | System | 06 Oct 2020 13:44:52 |
|                                                                                                                                                                                                                                                                                        | System | 06 Oct 2020 13:44:52 |

US3762161

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 11:14:36

**MUSCLE ACHES ALL OVER BODY**

| Audit                                                                                                                                                                                                                                                                                  | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-06T09:44:29', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '26aa56fd-1d85-4c51-adc8-63e550a2621b' User entered 'None (0)' | System | 06 Oct 2020 13:44:52 |
|                                                                                                                                                                                                                                                                                        | System | 06 Oct 2020 13:44:52 |

US3762161

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 11:14:36

**JOINT ACHES IN SEVERAL JOINTS**

| Audit                                                                                                                                                                                                                                                                                  | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-06T09:44:32', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '26aa56fd-1d85-4c51-adc8-63e550a2621b' User entered 'None (0)' | System | 06 Oct 2020 13:44:52 |
|                                                                                                                                                                                                                                                                                        | System | 06 Oct 2020 13:44:52 |

US3762161

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 11:14:36

**NAUSEA/VOMITING**

| Audit                                                                                                                                                                                                                                                                                  | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-06T09:44:35', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '26aa56fd-1d85-4c51-adc8-63e550a2621b' User entered 'None (0)' | System | 06 Oct 2020 13:44:52 |

US3762161

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 11:14:36

CHILLS

| Audit                                                                                                                                                                                                                                                                                  | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-06T09:44:38', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '26aa56fd-1d85-4c51-adc8-63e550a2621b' User entered 'None (0)' | System | 06 Oct 2020 13:44:52 |
|                                                                                                                                                                                                                                                                                        | System | 06 Oct 2020 13:44:52 |



US3762161

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 11:14:36

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 (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-06T09:44:44', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '26aa56fd-1d85-4c51-adc8-63e550a2621b' User entered 'No (N)' | System | 06 Oct 2020 13:44:52 |

**US3762161**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 11:14:36**

[PC Time stamp](#)

| Audit                                                                                                                                                                                                                                                                                           | User   | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-06T09:44:46', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '26aa56fd-1d85-4c51-adc8-63e550a2621b' User entered '06 Oct 2020 09:44' | System | 06 Oct 2020 13:44:52 |
|                                                                                                                                                                                                                                                                                                 | System | 06 Oct 2020 13:44:52 |

US3762161

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 11:14:36

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '05 Oct 2020 12:00' | System | 30 Sep 2020 20:25:41 |

US3762161

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 11:14:36

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '06 Oct 2020 11:59' | System | 30 Sep 2020 20:25:41 |

**US3762161**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 11:14:36**

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 30 Sep 2020 20:25:41 |
| User entered 'Day 7' | System | 30 Sep 2020 20:25:41 |

US3762161

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 11:14:36

**HEADACHE**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-06T21:30:57', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '903cfe7f-1cd6-4931-9111-23c647d5df53' | System | 07 Oct 2020 01:31:18 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 07 Oct 2020 01:31:18 |

US3762161

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 11:14:36

**FATIGUE**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-06T21:31:00', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '903cfe7f-1cd6-4931-9111-23c647d5df53' | System | 07 Oct 2020 01:31:18 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 07 Oct 2020 01:31:18 |

US3762161

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 11:14:36

**MUSCLE ACHES ALL OVER BODY**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-06T21:31:02', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '903cfe7f-1cd6-4931-9111-23c647d5df53' | System | 07 Oct 2020 01:31:18 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 07 Oct 2020 01:31:18 |



US3762161

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 11:14:36

**JOINT ACHES IN SEVERAL JOINTS**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-06T21:31:05', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '903cfe7f-1cd6-4931-9111-23c647d5df53' | System | 07 Oct 2020 01:31:18 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 07 Oct 2020 01:31:18 |

**US3762161**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 11:14:36**

**NAUSEA/VOMITING**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-06T21:31:07', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '903cfe7f-1cd6-4931-9111-23c647d5df53' | System | 07 Oct 2020 01:31:18 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 07 Oct 2020 01:31:18 |

**US3762161**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 11:14:36**

**CHILLS**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-06T21:31:10', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '903cfe7f-1cd6-4931-9111-23c647d5df53' | System | 07 Oct 2020 01:31:18 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 07 Oct 2020 01:31:18 |

US3762161

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 11:14:36

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 (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-06T21:31:14', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '903cfe7f-1cd6-4931-9111-23c647d5df53' | System | 07 Oct 2020 01:31:18 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 07 Oct 2020 01:31:18 |

**US3762161**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 11:14:36**

[PC Time stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-06T21:31:16', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '903cfe7f-1cd6-4931-9111-23c647d5df53' | System | 07 Oct 2020 01:31:18 |
| User entered '06 Oct 2020 21:31'                                                                                                                                                                                                                               | System | 07 Oct 2020 01:31:18 |

US3762161

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 11:14:36

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '06 Oct 2020 12:00' | System | 30 Sep 2020 20:25:41 |

US3762161

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 11:14:36

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '07 Oct 2020 11:59' | System | 30 Sep 2020 20:25:41 |

US3762161

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 11:14:36**

[Was Contact Attempted?](#)

| Audit                  | User                          | Time (GMT)           |
|------------------------|-------------------------------|----------------------|
| User entered 'Yes (Y)' | Kaitlyn Van Leuvan<br>(b) (4) | 21 Oct 2020 15:26:15 |



US3762161

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 11:14:36**

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

| Audit                      | User                          | Time (GMT)           |
|----------------------------|-------------------------------|----------------------|
| User entered '07 Oct 2020' | Kaitlyn Van Leuvan<br>(b) (4) | 21 Oct 2020 15:26:15 |

US3762161

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 11:14:36**

[Please select one status for the follow-up contact](#)

| Audit                                      | User                          | Time (GMT)           |
|--------------------------------------------|-------------------------------|----------------------|
| User entered 'Contact Made (CONTACT MADE)' | Kaitlyn Van Leuvan<br>(b) (4) | 21 Oct 2020 15:26:15 |

US3762161

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 11:14:36**

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit               | User                          | Time (GMT)           |
|---------------------|-------------------------------|----------------------|
| User entered empty. | Kaitlyn Van Leuvan<br>(b) (4) | 21 Oct 2020 15:26:15 |

US3762161

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 11:14:36**

[Is the participant continuing to the next visit?](#)

| Audit                  | User                          | Time (GMT)           |
|------------------------|-------------------------------|----------------------|
| User entered 'Yes (Y)' | Kaitlyn Van Leuvan<br>(b) (4) | 21 Oct 2020 15:26:21 |

**US3762161**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 11:14:36**

[Continuing Flag](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 21 Oct 2020 15:26:21 |

US3762161

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 11:14:36**

[Was Contact Attempted?](#)

| Audit                  | User                          | Time (GMT)           |
|------------------------|-------------------------------|----------------------|
| User entered 'Yes (Y)' | Kaitlyn Van Leuvan<br>(b) (4) | 21 Oct 2020 15:26:35 |

US3762161

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 11:14:36**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

| Audit                      | User                          | Time (GMT)           |
|----------------------------|-------------------------------|----------------------|
| User entered '14 Oct 2020' | Kaitlyn Van Leuvan<br>(b) (4) | 21 Oct 2020 15:26:35 |

US3762161

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 11:14:36**

[Please select one status for the follow-up contact](#)

| Audit                                      | User                          | Time (GMT)           |
|--------------------------------------------|-------------------------------|----------------------|
| User entered 'Contact Made (CONTACT MADE)' | Kaitlyn Van Leuvan<br>(b) (4) | 21 Oct 2020 15:26:35 |



US3762161

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:14:36

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit               | User                          | Time (GMT)           |
|---------------------|-------------------------------|----------------------|
| User entered empty. | Kaitlyn Van Leuvan<br>(b) (4) | 21 Oct 2020 15:26:35 |

US3762161

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:14:36

[Is the participant continuing to the next visit?](#)

| Audit                  | User                          | Time (GMT)           |
|------------------------|-------------------------------|----------------------|
| User entered 'Yes (Y)' | Kaitlyn Van Leuvan<br>(b) (4) | 21 Oct 2020 15:26:41 |

**US3762161**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 11:14:36**

[Continuing Flag](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 21 Oct 2020 15:26:41 |

US3762161

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 11:14:36**

[Was Contact Attempted?](#)

| Audit                  | User                          | Time (GMT)           |
|------------------------|-------------------------------|----------------------|
| User entered 'Yes (Y)' | Kaitlyn Van Leuvan<br>(b) (4) | 21 Oct 2020 15:26:54 |

US3762161

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:14:36

Date of Contact or Contact Attempt (dd MMM yyyy)

| Audit                                                                                                                                                                                                                                                | User                          | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------|----------------------|
| User closed query 'Safety Call Day 50 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).             | System                        | 21 Oct 2020 15:27:23 |
| Query 'Safety Call Day 50 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered by data change (Site from System). | System                        | 21 Oct 2020 15:27:23 |
| User entered '21 Oct 2020' reason for change: Data Entry Error                                                                                                                                                                                       | Kaitlyn Van Leuvan<br>(b) (4) | 21 Oct 2020 15:27:23 |
| User opened query 'Safety Call Day 50 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).             | System                        | 21 Oct 2020 15:26:54 |
| User entered '20 Oct 2020'                                                                                                                                                                                                                           | Kaitlyn Van Leuvan<br>(b) (4) | 21 Oct 2020 15:26:54 |

US3762161

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 11:14:36**

[Please select one status for the follow-up contact](#)

| Audit                                      | User                          | Time (GMT)           |
|--------------------------------------------|-------------------------------|----------------------|
| User entered 'Contact Made (CONTACT MADE)' | Kaitlyn Van Leuvan<br>(b) (4) | 21 Oct 2020 15:26:54 |

US3762161

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:14:36

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit               | User                          | Time (GMT)           |
|---------------------|-------------------------------|----------------------|
| User entered empty. | Kaitlyn Van Leuvan<br>(b) (4) | 21 Oct 2020 15:26:54 |

US3762161

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 11:14:36**

[Is the participant continuing to the next visit?](#)

| Audit                  | User                          | Time (GMT)           |
|------------------------|-------------------------------|----------------------|
| User entered 'Yes (Y)' | Kaitlyn Van Leuvan<br>(b) (4) | 21 Oct 2020 15:27:29 |



**US3762161**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 11:14:36**

[Continuing Flag](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 21 Oct 2020 15:27:29 |

US3762161

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:14:36

[Was this visit performed?](#)

| Audit                  | User                          | Time (GMT)           |
|------------------------|-------------------------------|----------------------|
| User entered 'Yes (Y)' | Kaitlyn Van Leuvan<br>(b) (4) | 03 Nov 2020 15:38:52 |

US3762161

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 26 Nov 2020 11:14:36**

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

| Audit                      | User                          | Time (GMT)           |
|----------------------------|-------------------------------|----------------------|
| User entered '03 Nov 2020' | Kaitlyn Van Leuvan<br>(b) (4) | 03 Nov 2020 15:38:52 |

US3762161

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:14:36

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

| Audit                          | User                          | Time (GMT)           |
|--------------------------------|-------------------------------|----------------------|
| User entered 'Clinic (Clinic)' | Kaitlyn Van Leuvan<br>(b) (4) | 03 Nov 2020 15:38:52 |

**US3762161**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 26 Nov 2020 11:14:36**

[Folder OID](#)

| Audit                 | User   | Time (GMT)           |
|-----------------------|--------|----------------------|
| User entered 'VISIT3' | System | 03 Nov 2020 15:38:52 |

US3762161

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:14:36

[Were vital signs assessed?](#)

| Audit                  | User                          | Time (GMT)           |
|------------------------|-------------------------------|----------------------|
| User entered 'Yes (Y)' | Kaitlyn Van Leuvan<br>(b) (4) | 03 Nov 2020 16:31:37 |

US3762161

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:14:36

Date of assessment (*dd MMM yyyy*)

| Audit                      | User                          | Time (GMT)           |
|----------------------------|-------------------------------|----------------------|
| User entered '03 Nov 2020' | Kaitlyn Van Leuvan<br>(b) (4) | 03 Nov 2020 16:31:37 |

US3762161

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:14:36

Time of assessment (00:00-23:59)

| Audit                | User                          | Time (GMT)           |
|----------------------|-------------------------------|----------------------|
| User entered '09:41' | Kaitlyn Van Leuvan<br>(b) (4) | 03 Nov 2020 16:31:37 |



**US3762161**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 11:14:36**

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

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '03 Nov 2020 09:41' | System | 03 Nov 2020 16:31:37 |

US3762161

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:14:36

Temperature (xxx.x)

| Audit                 | User                          | Time (GMT)           |
|-----------------------|-------------------------------|----------------------|
| User entered '97.7' F | Kaitlyn Van Leuvan<br>(b) (4) | 03 Nov 2020 16:31:37 |

US3762161

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 11:14:36**

[Route of measurement](#)

| Audit                      | User                          | Time (GMT)           |
|----------------------------|-------------------------------|----------------------|
| User entered 'Oral (Oral)' | Kaitlyn Van Leuvan<br>(b) (4) | 03 Nov 2020 16:31:37 |

US3762161

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:14:36

[If Other, specify](#)

| Audit               | User                          | Time (GMT)           |
|---------------------|-------------------------------|----------------------|
| User entered empty. | Kaitlyn Van Leuvan<br>(b) (4) | 03 Nov 2020 16:31:37 |

US3762161

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:14:36

[Pulse \(xxx\)](#)

| Audit             | User                          | Time (GMT)           |
|-------------------|-------------------------------|----------------------|
| User entered '65' | Kaitlyn Van Leuvan<br>(b) (4) | 03 Nov 2020 16:31:37 |

**US3762161**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 11:14:36**

[Pulse units](#)

| Audit              | User   | Time (GMT)           |
|--------------------|--------|----------------------|
| User entered 'bpm' | System | 03 Nov 2020 16:31:37 |

US3762161

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:14:36

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

| Audit             | User                          | Time (GMT)           |
|-------------------|-------------------------------|----------------------|
| User entered '16' | Kaitlyn Van Leuvan<br>(b) (4) | 03 Nov 2020 16:31:37 |

US3762161

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:14:36

[Respiratory Rate units](#)

| Audit                      | User   | Time (GMT)           |
|----------------------------|--------|----------------------|
| User entered 'breaths/min' | System | 03 Nov 2020 16:31:37 |



US3762161

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:14:36

Systolic Blood Pressure (xxx)

| Audit              | User                          | Time (GMT)           |
|--------------------|-------------------------------|----------------------|
| User entered '127' | Kaitlyn Van Leuvan<br>(b) (4) | 03 Nov 2020 16:31:37 |

US3762161

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:14:36

[Systolic Blood Pressure units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 03 Nov 2020 16:31:37 |

US3762161

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:14:36

Diastolic Blood Pressure (xxx)

| Audit             | User                          | Time (GMT)           |
|-------------------|-------------------------------|----------------------|
| User entered '67' | Kaitlyn Van Leuvan<br>(b) (4) | 03 Nov 2020 16:31:37 |

US3762161

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:14:36

[Diastolic Blood Pressure units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 03 Nov 2020 16:31:37 |

US3762161

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:14:36

[Was the physical examination performed?](#)

| Audit                 | User                          | Time (GMT)           |
|-----------------------|-------------------------------|----------------------|
| User entered 'No (N)' | Kaitlyn Van Leuvan<br>(b) (4) | 03 Nov 2020 16:31:48 |

US3762161

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:14:36

Date of examination (*dd MMM yyyy*)

| Audit               | User                          | Time (GMT)           |
|---------------------|-------------------------------|----------------------|
| User entered empty. | Kaitlyn Van Leuvan<br>(b) (4) | 03 Nov 2020 16:31:48 |

US3762161

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:14:36

[Was the sample collected?](#)

| Audit                  | User                          | Time (GMT)           |
|------------------------|-------------------------------|----------------------|
| User entered 'Yes (Y)' | Kaitlyn Van Leuvan<br>(b) (4) | 03 Nov 2020 16:32:05 |

US3762161

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 26 Nov 2020 11:14:36**

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

| Audit                      | User                          | Time (GMT)           |
|----------------------------|-------------------------------|----------------------|
| User entered '03 Nov 2020' | Kaitlyn Van Leuvan<br>(b) (4) | 03 Nov 2020 16:32:05 |



US3762161

**Folder:** Visit 3 Day 57 (1)

**Form:** Immunogenicity Assessment

**Generated On:** 26 Nov 2020 11:14:36

[Collection time \(00:00-23:59\)](#)

| Audit                | User                          | Time (GMT)           |
|----------------------|-------------------------------|----------------------|
| User entered '10:03' | Kaitlyn Van Leuvan<br>(b) (4) | 03 Nov 2020 16:32:05 |

**US3762161**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 26 Nov 2020 11:14:36**

[Collection date and time \(derived\)](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '03 Nov 2020 10:03' | System | 03 Nov 2020 16:32:05 |

US3762161

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:14:36

[Is the participant continuing to the next visit?](#)

| Audit                  | User                          | Time (GMT)           |
|------------------------|-------------------------------|----------------------|
| User entered 'Yes (Y)' | Kaitlyn Van Leuvan<br>(b) (4) | 03 Nov 2020 16:32:10 |

**US3762161**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 11:14:36**

[Continuing Flag](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 03 Nov 2020 16:32:10 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

**TIMEPOINT**

| Audit                 | User   | Time (GMT)           |
|-----------------------|--------|----------------------|
| Data entry locked.    | System | 02 Sep 2020 19:29:34 |
| User entered 'Day 64' | System | 02 Sep 2020 19:29:34 |

US3762161

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

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 (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-11-02T22:42:12', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: 'f0a02ba5-e26d-4b63-b3a6-c6a74ea0ac3d' | System | 03 Nov 2020 03:42:28 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 03 Nov 2020 03:42:28 |

US3762161

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

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 (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-11-02T22:42:16', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: 'f0a02ba5-e26d-4b63-b3a6-c6a74ea0ac3d' | System | 03 Nov 2020 03:42:28 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 03 Nov 2020 03:42:28 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

[Date and time of submission](#)

| Audit                                                                                                                                                                                                                                                                                              | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-11-02T22:42:24', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: 'f0a02ba5-e26d-4b63-b3a6-c6a74ea0ac3d' User entered '02 Nov 2020 22:42:24' | System | 03 Nov 2020 03:42:28 |
|                                                                                                                                                                                                                                                                                                    | System | 03 Nov 2020 03:42:28 |



**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

[Patient Cloud Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| Data entry locked.               | System | 02 Sep 2020 19:29:34 |
| User entered '02 Nov 2020 00:01' | System | 02 Sep 2020 19:29:34 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

[Patient Cloud Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| Data entry locked.               | System | 02 Sep 2020 19:29:34 |
| User entered '06 Nov 2020 23:59' | System | 02 Sep 2020 19:29:34 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

**TIMEPOINT**

| Audit                                    | User   | Time (GMT)           |
|------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.    | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered 'Day 61' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '30 Oct 2020 00:01' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '03 Nov 2020 23:59' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

**TIMEPOINT**

| Audit                                    | User   | Time (GMT)           |
|------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.    | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered 'Day 68' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '06 Nov 2020 00:01' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '10 Nov 2020 23:59' | System | 20 Nov 2020 02:50:20 |



**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

**TIMEPOINT**

| Audit                                    | User   | Time (GMT)           |
|------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.    | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered 'Day 75' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '13 Nov 2020 00:01' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '17 Nov 2020 23:59' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

**TIMEPOINT**

| Audit                                    | User   | Time (GMT)           |
|------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.    | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered 'Day 82' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '20 Nov 2020 00:01' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '24 Nov 2020 23:59' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

**TIMEPOINT**

| Audit                                    | User   | Time (GMT)           |
|------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.    | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered 'Day 89' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '27 Nov 2020 00:01' | System | 20 Nov 2020 02:50:20 |



**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '01 Dec 2020 23:59' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

**TIMEPOINT**

| Audit                                    | User   | Time (GMT)           |
|------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.    | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered 'Day 96' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '04 Dec 2020 00:01' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '08 Dec 2020 23:59' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered 'Day 103' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '11 Dec 2020 00:01' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '15 Dec 2020 23:59' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered 'Day 110' | System | 20 Nov 2020 02:50:20 |



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '18 Dec 2020 00:01' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '22 Dec 2020 23:59' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered 'Day 117' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '25 Dec 2020 00:01' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '29 Dec 2020 23:59' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered 'Day 124' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '01 Jan 2021 00:01' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '05 Jan 2021 23:59' | System | 20 Nov 2020 02:50:20 |



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered 'Day 131' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '08 Jan 2021 00:01' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '12 Jan 2021 23:59' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered 'Day 138' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '15 Jan 2021 00:01' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '19 Jan 2021 23:59' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered 'Day 145' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '22 Jan 2021 00:01' | System | 20 Nov 2020 02:50:20 |



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '26 Jan 2021 23:59' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered 'Day 152' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '29 Jan 2021 00:01' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '02 Feb 2021 23:59' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered 'Day 159' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '05 Feb 2021 00:01' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '09 Feb 2021 23:59' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered 'Day 166' | System | 20 Nov 2020 02:50:20 |



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '12 Feb 2021 00:01' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '16 Feb 2021 23:59' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered 'Day 173' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '19 Feb 2021 00:01' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '23 Feb 2021 23:59' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered 'Day 180' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '26 Feb 2021 00:01' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '02 Mar 2021 23:59' | System | 20 Nov 2020 02:50:20 |



**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered 'Day 187' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '05 Mar 2021 00:01' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '09 Mar 2021 23:59' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered 'Day 194' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '12 Mar 2021 00:01' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '16 Mar 2021 23:59' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered 'Day 201' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '19 Mar 2021 00:01' | System | 20 Nov 2020 02:50:20 |



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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 | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '23 Mar 2021 23:59' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered 'Day 208' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '26 Mar 2021 00:01' | System | 20 Nov 2020 02:50:20 |

**US3762161**

**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 | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '30 Mar 2021 23:59' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

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**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered 'Day 215' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '02 Apr 2021 00:01' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '06 Apr 2021 23:59' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered 'Day 222' | System | 20 Nov 2020 02:50:20 |



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '09 Apr 2021 00:01' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '13 Apr 2021 23:59' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered 'Day 229' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '16 Apr 2021 00:01' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '20 Apr 2021 23:59' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered 'Day 236' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '23 Apr 2021 00:01' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '27 Apr 2021 23:59' | System | 20 Nov 2020 02:50:20 |



**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered 'Day 243' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '30 Apr 2021 00:01' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '04 May 2021 23:59' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered 'Day 250' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '07 May 2021 00:01' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '11 May 2021 23:59' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered 'Day 257' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '14 May 2021 00:01' | System | 20 Nov 2020 02:50:20 |



**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '18 May 2021 23:59' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered 'Day 264' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '21 May 2021 00:01' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '25 May 2021 23:59' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered 'Day 271' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '28 May 2021 00:01' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '01 Jun 2021 23:59' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered 'Day 278' | System | 20 Nov 2020 02:50:20 |



**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '04 Jun 2021 00:01' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '08 Jun 2021 23:59' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered 'Day 285' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '11 Jun 2021 00:01' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '15 Jun 2021 23:59' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered 'Day 292' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '18 Jun 2021 00:01' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '22 Jun 2021 23:59' | System | 20 Nov 2020 02:50:20 |



**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered 'Day 299' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '25 Jun 2021 00:01' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '29 Jun 2021 23:59' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered 'Day 306' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '02 Jul 2021 00:01' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '06 Jul 2021 23:59' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered 'Day 313' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '09 Jul 2021 00:01' | System | 20 Nov 2020 02:50:20 |



**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '13 Jul 2021 23:59' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered 'Day 320' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '16 Jul 2021 00:01' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '20 Jul 2021 23:59' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered 'Day 327' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '23 Jul 2021 00:01' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '27 Jul 2021 23:59' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered 'Day 334' | System | 20 Nov 2020 02:50:20 |



**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '30 Jul 2021 00:01' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '03 Aug 2021 23:59' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered 'Day 341' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '06 Aug 2021 00:01' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '10 Aug 2021 23:59' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered 'Day 348' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '13 Aug 2021 00:01' | System | 20 Nov 2020 02:50:20 |

**US3762161**

**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 | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '17 Aug 2021 23:59' | System | 20 Nov 2020 02:50:20 |



**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered 'Day 355' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '20 Aug 2021 00:01' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

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[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '24 Aug 2021 23:59' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered 'Day 362' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

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[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '27 Aug 2021 00:01' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '31 Aug 2021 23:59' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered 'Day 369' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '03 Sep 2021 00:01' | System | 20 Nov 2020 02:50:20 |



**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '07 Sep 2021 23:59' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered 'Day 376' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '10 Sep 2021 00:01' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '14 Sep 2021 23:59' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered 'Day 383' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '17 Sep 2021 00:01' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '21 Sep 2021 23:59' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered 'Day 390' | System | 20 Nov 2020 02:50:20 |



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '24 Sep 2021 00:01' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '28 Sep 2021 23:59' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered 'Day 397' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '01 Oct 2021 00:01' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '05 Oct 2021 23:59' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered 'Day 404' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '08 Oct 2021 00:01' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '12 Oct 2021 23:59' | System | 20 Nov 2020 02:50:20 |



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered 'Day 411' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '15 Oct 2021 00:01' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '19 Oct 2021 23:59' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered 'Day 418' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '22 Oct 2021 00:01' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '26 Oct 2021 23:59' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered 'Day 425' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '29 Oct 2021 00:01' | System | 20 Nov 2020 02:50:20 |



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '02 Nov 2021 23:59' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered 'Day 432' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '05 Nov 2021 00:01' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '09 Nov 2021 23:59' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered 'Day 439' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '12 Nov 2021 00:01' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '16 Nov 2021 23:59' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered 'Day 446' | System | 20 Nov 2020 02:50:20 |



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '19 Nov 2021 00:01' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '23 Nov 2021 23:59' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered 'Day 453' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '26 Nov 2021 00:01' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '30 Nov 2021 23:59' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered 'Day 460' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '03 Dec 2021 00:01' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '07 Dec 2021 23:59' | System | 20 Nov 2020 02:50:20 |



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered 'Day 467' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '10 Dec 2021 00:01' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '14 Dec 2021 23:59' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered 'Day 474' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '17 Dec 2021 00:01' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '21 Dec 2021 23:59' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered 'Day 481' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '24 Dec 2021 00:01' | System | 20 Nov 2020 02:50:20 |



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '28 Dec 2021 23:59' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered 'Day 488' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '31 Dec 2021 00:01' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

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| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '04 Jan 2022 23:59' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

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**Generated On: 26 Nov 2020 11:14:36**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered 'Day 495' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

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**Generated On: 26 Nov 2020 11:14:36**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '07 Jan 2022 00:01' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

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| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '11 Jan 2022 23:59' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered 'Day 502' | System | 20 Nov 2020 02:50:20 |



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

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**Generated On: 26 Nov 2020 11:14:36**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '14 Jan 2022 00:01' | System | 20 Nov 2020 02:50:20 |

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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 | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '18 Jan 2022 23:59' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered 'Day 509' | System | 20 Nov 2020 02:50:20 |

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '21 Jan 2022 00:01' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '25 Jan 2022 23:59' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered 'Day 516' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '28 Jan 2022 00:01' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '01 Feb 2022 23:59' | System | 20 Nov 2020 02:50:20 |



**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered 'Day 523' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '04 Feb 2022 00:01' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '08 Feb 2022 23:59' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered 'Day 530' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '11 Feb 2022 00:01' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '15 Feb 2022 23:59' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered 'Day 537' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '18 Feb 2022 00:01' | System | 20 Nov 2020 02:50:20 |



**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '22 Feb 2022 23:59' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered 'Day 544' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '25 Feb 2022 00:01' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '01 Mar 2022 23:59' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered 'Day 551' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '04 Mar 2022 00:01' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '08 Mar 2022 23:59' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered 'Day 558' | System | 20 Nov 2020 02:50:20 |



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '11 Mar 2022 00:01' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '15 Mar 2022 23:59' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered 'Day 565' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '18 Mar 2022 00:01' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '22 Mar 2022 23:59' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered 'Day 572' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '25 Mar 2022 00:01' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '29 Mar 2022 23:59' | System | 20 Nov 2020 02:50:20 |



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered 'Day 579' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '01 Apr 2022 00:01' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '05 Apr 2022 23:59' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered 'Day 586' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '08 Apr 2022 00:01' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '12 Apr 2022 23:59' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered 'Day 593' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '15 Apr 2022 00:01' | System | 20 Nov 2020 02:50:20 |



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '19 Apr 2022 23:59' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered 'Day 600' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '22 Apr 2022 00:01' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '26 Apr 2022 23:59' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered 'Day 607' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '29 Apr 2022 00:01' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

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| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '03 May 2022 23:59' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered 'Day 614' | System | 20 Nov 2020 02:50:20 |



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '06 May 2022 00:01' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '10 May 2022 23:59' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered 'Day 621' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '13 May 2022 00:01' | System | 20 Nov 2020 02:50:20 |

**US3762161**

**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 | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '17 May 2022 23:59' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered 'Day 628' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '20 May 2022 00:01' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

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| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '24 May 2022 23:59' | System | 20 Nov 2020 02:50:20 |



**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered 'Day 635' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '27 May 2022 00:01' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '31 May 2022 23:59' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered 'Day 642' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

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**Generated On: 26 Nov 2020 11:14:36**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '03 Jun 2022 00:01' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

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| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '07 Jun 2022 23:59' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered 'Day 649' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '10 Jun 2022 00:01' | System | 20 Nov 2020 02:50:20 |



**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '14 Jun 2022 23:59' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered 'Day 656' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '17 Jun 2022 00:01' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '21 Jun 2022 23:59' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered 'Day 663' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '24 Jun 2022 00:01' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '28 Jun 2022 23:59' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered 'Day 670' | System | 20 Nov 2020 02:50:20 |



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '01 Jul 2022 00:01' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '05 Jul 2022 23:59' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered 'Day 677' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '08 Jul 2022 00:01' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '12 Jul 2022 23:59' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered 'Day 684' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '15 Jul 2022 00:01' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

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| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '19 Jul 2022 23:59' | System | 20 Nov 2020 02:50:20 |



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered 'Day 691' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '22 Jul 2022 00:01' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

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| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '26 Jul 2022 23:59' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered 'Day 698' | System | 20 Nov 2020 02:50:20 |

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '29 Jul 2022 00:01' | System | 20 Nov 2020 02:50:20 |

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '02 Aug 2022 23:59' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered 'Day 705' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '05 Aug 2022 00:01' | System | 20 Nov 2020 02:50:20 |



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '09 Aug 2022 23:59' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered 'Day 712' | System | 20 Nov 2020 02:50:20 |

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '12 Aug 2022 00:01' | System | 20 Nov 2020 02:50:20 |

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

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[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '16 Aug 2022 23:59' | System | 20 Nov 2020 02:50:20 |

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered 'Day 719' | System | 20 Nov 2020 02:50:20 |

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '19 Aug 2022 00:01' | System | 20 Nov 2020 02:50:20 |

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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 | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '23 Aug 2022 23:59' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered 'Day 726' | System | 20 Nov 2020 02:50:20 |



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '26 Aug 2022 00:01' | System | 20 Nov 2020 02:50:20 |

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '30 Aug 2022 23:59' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered 'Day 733' | System | 20 Nov 2020 02:50:20 |

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '02 Sep 2022 00:01' | System | 20 Nov 2020 02:50:20 |

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '06 Sep 2022 23:59' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered 'Day 740' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '09 Sep 2022 00:01' | System | 20 Nov 2020 02:50:20 |

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

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| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '13 Sep 2022 23:59' | System | 20 Nov 2020 02:50:20 |



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

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**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered 'Day 747' | System | 20 Nov 2020 02:50:20 |

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '16 Sep 2022 00:01' | System | 20 Nov 2020 02:50:20 |

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

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**Generated On: 26 Nov 2020 11:14:36**

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| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '20 Sep 2022 23:59' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

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**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered 'Day 754' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '23 Sep 2022 00:01' | System | 20 Nov 2020 02:50:20 |

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

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**Generated On: 26 Nov 2020 11:14:36**

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| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '27 Sep 2022 23:59' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered 'Day 761' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '30 Sep 2022 00:01' | System | 20 Nov 2020 02:50:20 |



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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 | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '04 Oct 2022 23:59' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered 'Day 768' | System | 20 Nov 2020 02:50:20 |

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

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**Generated On: 26 Nov 2020 11:14:36**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '07 Oct 2022 00:01' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

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| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '11 Oct 2022 23:59' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

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| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered 'Day 775' | System | 20 Nov 2020 02:50:20 |

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

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**Generated On: 26 Nov 2020 11:14:36**

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| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '14 Oct 2022 00:01' | System | 20 Nov 2020 02:50:20 |

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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 | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '18 Oct 2022 23:59' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

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**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered 'Day 782' | System | 20 Nov 2020 02:50:20 |



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**Generated On: 26 Nov 2020 11:14:36**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '21 Oct 2022 00:01' | System | 20 Nov 2020 02:50:20 |

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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 | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '25 Oct 2022 23:59' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered 'Day 789' | System | 20 Nov 2020 02:50:20 |

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

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**Generated On: 26 Nov 2020 11:14:36**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '28 Oct 2022 00:01' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '01 Nov 2022 23:59' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered 'Day 796' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '04 Nov 2022 00:01' | System | 20 Nov 2020 02:50:20 |

**US3762161**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:14:36**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:50:20 |
| Amendment Manager: User entered '08 Nov 2022 23:59' | System | 20 Nov 2020 02:50:20 |



US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 11:14:36

[Date of Contact](#)

| Audit                     | User             | Time (GMT)           |
|---------------------------|------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6) | 19 Nov 2020 18:04:23 |
| User entered '9 Nov 2020' | (b) (4), (b) (6) | 10 Nov 2020 21:33:33 |

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 11:14:36

[Time of Contact](#)

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| DataPoint Verified.  | (b) (4), (b) (6) | 19 Nov 2020 18:04:23 |
| User entered '14:25' | (b) (4), (b) (6) | 10 Nov 2020 21:33:33 |

**US3762161**

**Folder: Covid-19 Assessment 09 Nov 2020**

**Form: COVID-19 Contact**

**Generated On: 26 Nov 2020 11:14:36**

[Date and Time of Contact \(derived\)](#)

| Audit                           | User   | Time (GMT)           |
|---------------------------------|--------|----------------------|
| User entered '9 Nov 2020 14:25' | System | 10 Nov 2020 21:33:33 |

**US3762161**

**Folder: Covid-19 Assessment 09 Nov 2020**

**Form: COVID-19 Contact**

**Generated On: 26 Nov 2020 11:14:36**

[Type of Contact](#)

| Audit                                                                      | User             | Time (GMT)           |
|----------------------------------------------------------------------------|------------------|----------------------|
| DataPoint Verified.                                                        | (b) (4), (b) (6) | 19 Nov 2020 18:04:23 |
| User entered 'Clinical Visit - Unscheduled (Clinical Visit - Unscheduled)' | (b) (4), (b) (6) | 10 Nov 2020 21:33:33 |

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 11:14:36

[Has the subject reported symptoms of SARS-COV-2?](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 19 Nov 2020 18:04:23 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 10 Nov 2020 21:33:33 |

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:14:36

[Symptom Day](#)

| Audit                                           | User                     | Time (GMT)           |
|-------------------------------------------------|--------------------------|----------------------|
| User entered 'Day 5 (Day 5)' reason for change: | Samantha Wheeler (b) (4) | 19 Nov 2020 21:35:32 |
| Data Entry Error                                | (b) (4)                  |                      |
| User entered 'Day 1 (Day 1)'                    | (b) (4), (b) (6)         | 10 Nov 2020 21:35:06 |
|                                                 |                          |                      |

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:14:36

[Date](#)

| Audit                     | User             | Time (GMT)           |
|---------------------------|------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6) | 19 Nov 2020 18:04:36 |
| User entered '9 Nov 2020' | (b) (4), (b) (6) | 10 Nov 2020 21:35:06 |

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:14:36

[Assessment Not Done](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 19 Nov 2020 18:04:36 |
| User entered '0'    | (b) (4), (b) (6) | 10 Nov 2020 21:35:06 |



US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:14:36

[O2 Saturation](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 19 Nov 2020 18:04:36 |
| User entered '95'   | (b) (4), (b) (6) | 10 Nov 2020 21:35:06 |

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:14:36

[O2 Saturation Units](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '%' | System | 10 Nov 2020 21:35:06 |

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:14:36

[Temperature](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 19 Nov 2020 18:04:36 |
| User entered '98.4' F | (b) (4), (b) (6) | 10 Nov 2020 21:35:06 |

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:14:36

[Chills](#)

| Audit                              | User             | Time (GMT)           |
|------------------------------------|------------------|----------------------|
| DataPoint Verified.                | (b) (4), (b) (6) | 19 Nov 2020 18:04:36 |
| User entered 'Moderate (Moderate)' | (b) (4), (b) (6) | 10 Nov 2020 21:35:06 |

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:14:36

[Cough](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 19 Nov 2020 18:04:36 |
| User entered 'Mild (Mild)' | (b) (4), (b) (6) | 10 Nov 2020 21:35:06 |

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:14:36

[Shortness of Breath](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 19 Nov 2020 18:04:36 |
| User entered 'None (None)' | (b) (4), (b) (6) | 10 Nov 2020 21:35:06 |

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:14:36

[Difficulty Breathing](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 19 Nov 2020 18:04:36 |
| User entered 'None (None)' | (b) (4), (b) (6) | 10 Nov 2020 21:35:06 |

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:14:36

[Fatigue](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 19 Nov 2020 18:04:36 |
| User entered 'None (None)' | (b) (4), (b) (6) | 10 Nov 2020 21:35:06 |



US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:14:36

[Muscle Aches \(Myalgia\)](#)

| Audit                              | User             | Time (GMT)           |
|------------------------------------|------------------|----------------------|
| DataPoint Verified.                | (b) (4), (b) (6) | 19 Nov 2020 18:04:36 |
| User entered 'Moderate (Moderate)' | (b) (4), (b) (6) | 10 Nov 2020 21:35:06 |

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:14:36

[Body Aches](#)

| Audit                              | User             | Time (GMT)           |
|------------------------------------|------------------|----------------------|
| DataPoint Verified.                | (b) (4), (b) (6) | 19 Nov 2020 18:04:36 |
| User entered 'Moderate (Moderate)' | (b) (4), (b) (6) | 10 Nov 2020 21:35:06 |

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:14:36

[Headache](#)

| Audit                          | User             | Time (GMT)           |
|--------------------------------|------------------|----------------------|
| DataPoint Verified.            | (b) (4), (b) (6) | 19 Nov 2020 18:04:36 |
| User entered 'Severe (Severe)' | (b) (4), (b) (6) | 10 Nov 2020 21:35:06 |

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:14:36

[New Loss of Taste](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 19 Nov 2020 18:04:36 |
| User entered 'None (None)' | (b) (4), (b) (6) | 10 Nov 2020 21:35:06 |

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:14:36

[New Loss of Smell](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 19 Nov 2020 18:04:36 |
| User entered 'None (None)' | (b) (4), (b) (6) | 10 Nov 2020 21:35:06 |

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:14:36

[Nasal Congestion](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 19 Nov 2020 18:04:36 |
| User entered 'None (None)' | (b) (4), (b) (6) | 10 Nov 2020 21:35:06 |

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:14:36

[Runny Nose \(Rhinorrhea\)](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 19 Nov 2020 18:04:36 |
| User entered 'None (None)' | (b) (4), (b) (6) | 10 Nov 2020 21:35:06 |

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:14:36

[Nausea](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 19 Nov 2020 18:04:36 |
| User entered 'None (None)' | (b) (4), (b) (6) | 10 Nov 2020 21:35:06 |



US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:14:36

[Vomiting](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 19 Nov 2020 18:04:36 |
| User entered 'None (None)' | (b) (4), (b) (6) | 10 Nov 2020 21:35:06 |

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:14:36

[Diarrhea](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 19 Nov 2020 18:04:36 |
| User entered 'None (None)' | (b) (4), (b) (6) | 10 Nov 2020 21:35:06 |

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:14:36

[Sore Throat](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 19 Nov 2020 18:04:36 |
| User entered 'Mild (Mild)' | (b) (4), (b) (6) | 10 Nov 2020 21:35:06 |

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:14:36

[Symptom Day](#)

| Audit                        | User                     | Time (GMT)           |
|------------------------------|--------------------------|----------------------|
| User entered 'Day 1 (Day 1)' | Samantha Wheeler (b) (4) | 19 Nov 2020 21:36:42 |
|                              | (b) (4)                  |                      |

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:14:36

[Date](#)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)         | 19 Nov 2020 21:50:54 |
| User entered '05 Nov 2020' | Samantha Wheeler (b) (4) | 19 Nov 2020 21:36:42 |
|                            | (b) (4)                  |                      |

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:14:36

[Assessment Not Done](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 19 Nov 2020 21:50:54 |
| User entered '0'    | Samantha Wheeler (b) (4) | 19 Nov 2020 21:36:42 |
|                     | (b) (4)                  |                      |

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:14:36

[O2 Saturation](#)

| Audit                                    | User                     | Time (GMT)           |
|------------------------------------------|--------------------------|----------------------|
| DataPoint Verified.                      | (b) (4), (b) (6)         | 19 Nov 2020 21:50:54 |
| User entered missing code ND - Not Done. | Samantha Wheeler (b) (4) | 19 Nov 2020 21:36:42 |
|                                          | (b) (4)                  |                      |

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:14:36

[O2 Saturation Units](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '%' | System | 19 Nov 2020 21:36:42 |



US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:14:36

[Temperature](#)

| Audit                                    | User                     | Time (GMT)           |
|------------------------------------------|--------------------------|----------------------|
| DataPoint Verified.                      | (b) (4), (b) (6)         | 19 Nov 2020 21:50:54 |
| User entered missing code ND - Not Done. | Samantha Wheeler (b) (4) | 19 Nov 2020 21:36:42 |
|                                          | (b) (4)                  |                      |

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:14:36

[Chills](#)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)         | 19 Nov 2020 21:50:54 |
| User entered 'None (None)' | Samantha Wheeler (b) (4) | 19 Nov 2020 21:36:42 |
|                            | (b) (4)                  |                      |

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:14:36

[Cough](#)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)         | 19 Nov 2020 21:50:54 |
| User entered 'None (None)' | Samantha Wheeler (b) (4) | 19 Nov 2020 21:36:42 |
|                            | (b) (4)                  |                      |

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:14:36

[Shortness of Breath](#)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)         | 19 Nov 2020 21:50:54 |
| User entered 'None (None)' | Samantha Wheeler (b) (4) | 19 Nov 2020 21:36:42 |
|                            | (b) (4)                  |                      |

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:14:36

[Difficulty Breathing](#)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)         | 19 Nov 2020 21:50:54 |
| User entered 'None (None)' | Samantha Wheeler (b) (4) | 19 Nov 2020 21:36:42 |
|                            | (b) (4)                  |                      |

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:14:36

[Fatigue](#)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)         | 19 Nov 2020 21:50:54 |
| User entered 'Mild (Mild)' | Samantha Wheeler (b) (4) | 19 Nov 2020 21:36:42 |
|                            | (b) (4)                  |                      |

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:14:36

[Muscle Aches \(Myalgia\)](#)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)         | 19 Nov 2020 21:50:54 |
| User entered 'None (None)' | Samantha Wheeler (b) (4) | 19 Nov 2020 21:36:42 |
|                            | (b) (4)                  |                      |

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:14:36

[Body Aches](#)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)         | 19 Nov 2020 21:50:54 |
| User entered 'None (None)' | Samantha Wheeler (b) (4) | 19 Nov 2020 21:36:42 |
|                            | (b) (4)                  |                      |



US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:14:36

[Headache](#)

| Audit                          | User                     | Time (GMT)           |
|--------------------------------|--------------------------|----------------------|
| DataPoint Verified.            | (b) (4), (b) (6)         | 19 Nov 2020 21:50:54 |
| User entered 'Severe (Severe)' | Samantha Wheeler (b) (4) | 19 Nov 2020 21:36:42 |
|                                | (b) (4)                  |                      |

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:14:36

[New Loss of Taste](#)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)         | 19 Nov 2020 21:50:54 |
| User entered 'None (None)' | Samantha Wheeler (b) (4) | 19 Nov 2020 21:36:42 |
|                            | (b) (4)                  |                      |

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:14:36

[New Loss of Smell](#)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)         | 19 Nov 2020 21:50:54 |
| User entered 'None (None)' | Samantha Wheeler (b) (4) | 19 Nov 2020 21:36:42 |
|                            | (b) (4)                  |                      |

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:14:36

[Nasal Congestion](#)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)         | 19 Nov 2020 21:50:54 |
| User entered 'None (None)' | Samantha Wheeler (b) (4) | 19 Nov 2020 21:36:42 |
|                            | (b) (4)                  |                      |

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:14:36

[Runny Nose \(Rhinorrhea\)](#)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)         | 19 Nov 2020 21:50:54 |
| User entered 'None (None)' | Samantha Wheeler (b) (4) | 19 Nov 2020 21:36:42 |
|                            | (b) (4)                  |                      |

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:14:36

[Nausea](#)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)         | 19 Nov 2020 21:50:54 |
| User entered 'None (None)' | Samantha Wheeler (b) (4) | 19 Nov 2020 21:36:42 |
|                            | (b) (4)                  |                      |

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:14:36

[Vomiting](#)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)         | 19 Nov 2020 21:50:54 |
| User entered 'None (None)' | Samantha Wheeler (b) (4) | 19 Nov 2020 21:36:42 |
|                            | (b) (4)                  |                      |

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:14:36

[Diarrhea](#)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)         | 19 Nov 2020 21:50:54 |
| User entered 'Mild (Mild)' | Samantha Wheeler (b) (4) | 19 Nov 2020 21:36:42 |
|                            | (b) (4)                  |                      |



US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:14:36

[Sore Throat](#)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)         | 19 Nov 2020 21:50:54 |
| User entered 'None (None)' | Samantha Wheeler (b) (4) | 19 Nov 2020 21:36:42 |
|                            | (b) (4)                  |                      |

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:14:36

[Symptom Day](#)

| Audit                        | User                     | Time (GMT)           |
|------------------------------|--------------------------|----------------------|
| User entered 'Day 2 (Day 2)' | Samantha Wheeler (b) (4) | 19 Nov 2020 21:37:52 |
|                              | (b) (4)                  |                      |

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:14:36

[Date](#)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)         | 19 Nov 2020 21:50:54 |
| User entered '06 Nov 2020' | Samantha Wheeler (b) (4) | 19 Nov 2020 21:37:52 |
|                            | (b) (4)                  |                      |

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:14:36

[Assessment Not Done](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 19 Nov 2020 21:50:54 |
| User entered '0'    | Samantha Wheeler (b) (4) | 19 Nov 2020 21:37:52 |
|                     | (b) (4)                  |                      |

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:14:36

[O2 Saturation](#)

| Audit                                    | User                     | Time (GMT)           |
|------------------------------------------|--------------------------|----------------------|
| DataPoint Verified.                      | (b) (4), (b) (6)         | 19 Nov 2020 21:50:54 |
| User entered missing code ND - Not Done. | Samantha Wheeler (b) (4) | 19 Nov 2020 21:37:52 |
|                                          | (b) (4)                  |                      |

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:14:36

[O2 Saturation Units](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '%' | System | 19 Nov 2020 21:37:52 |

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:14:36

[Temperature](#)

| Audit                                    | User                     | Time (GMT)           |
|------------------------------------------|--------------------------|----------------------|
| DataPoint Verified.                      | (b) (4), (b) (6)         | 19 Nov 2020 21:50:54 |
| User entered missing code ND - Not Done. | Samantha Wheeler (b) (4) | 19 Nov 2020 21:37:52 |
|                                          | (b) (4)                  |                      |

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:14:36

[Chills](#)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)         | 19 Nov 2020 21:50:54 |
| User entered 'None (None)' | Samantha Wheeler (b) (4) | 19 Nov 2020 21:37:52 |
|                            | (b) (4)                  |                      |



US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:14:36

[Cough](#)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)         | 19 Nov 2020 21:50:54 |
| User entered 'None (None)' | Samantha Wheeler (b) (4) | 19 Nov 2020 21:37:52 |
|                            | (b) (4)                  |                      |

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:14:36

[Shortness of Breath](#)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)         | 19 Nov 2020 21:50:54 |
| User entered 'None (None)' | Samantha Wheeler (b) (4) | 19 Nov 2020 21:37:52 |
|                            | (b) (4)                  |                      |

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:14:36

[Difficulty Breathing](#)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)         | 19 Nov 2020 21:50:54 |
| User entered 'None (None)' | Samantha Wheeler (b) (4) | 19 Nov 2020 21:37:52 |
|                            | (b) (4)                  |                      |

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:14:36

[Fatigue](#)

| Audit                              | User                     | Time (GMT)           |
|------------------------------------|--------------------------|----------------------|
| DataPoint Verified.                | (b) (4), (b) (6)         | 19 Nov 2020 21:50:54 |
| User entered 'Moderate (Moderate)' | Samantha Wheeler (b) (4) | 19 Nov 2020 21:37:52 |
|                                    | (b) (4)                  |                      |

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:14:36

[Muscle Aches \(Myalgia\)](#)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)         | 19 Nov 2020 21:50:54 |
| User entered 'None (None)' | Samantha Wheeler (b) (4) | 19 Nov 2020 21:37:52 |
|                            | (b) (4)                  |                      |

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:14:36

[Body Aches](#)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)         | 19 Nov 2020 21:50:54 |
| User entered 'None (None)' | Samantha Wheeler (b) (4) | 19 Nov 2020 21:37:52 |
|                            | (b) (4)                  |                      |

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:14:36

[Headache](#)

| Audit                          | User                     | Time (GMT)           |
|--------------------------------|--------------------------|----------------------|
| DataPoint Verified.            | (b) (4), (b) (6)         | 19 Nov 2020 21:50:54 |
| User entered 'Severe (Severe)' | Samantha Wheeler (b) (4) | 19 Nov 2020 21:37:52 |
|                                | (b) (4)                  |                      |

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:14:36

[New Loss of Taste](#)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)         | 19 Nov 2020 21:50:54 |
| User entered 'None (None)' | Samantha Wheeler (b) (4) | 19 Nov 2020 21:37:52 |
|                            | (b) (4)                  |                      |



US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:14:36

[New Loss of Smell](#)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)         | 19 Nov 2020 21:50:54 |
| User entered 'None (None)' | Samantha Wheeler (b) (4) | 19 Nov 2020 21:37:52 |
|                            | (b) (4)                  |                      |

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:14:36

[Nasal Congestion](#)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)         | 19 Nov 2020 21:50:54 |
| User entered 'None (None)' | Samantha Wheeler (b) (4) | 19 Nov 2020 21:37:52 |
|                            | (b) (4)                  |                      |

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:14:36

[Runny Nose \(Rhinorrhea\)](#)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)         | 19 Nov 2020 21:50:54 |
| User entered 'None (None)' | Samantha Wheeler (b) (4) | 19 Nov 2020 21:37:52 |
|                            | (b) (4)                  |                      |

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:14:36

[Nausea](#)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)         | 19 Nov 2020 21:50:54 |
| User entered 'None (None)' | Samantha Wheeler (b) (4) | 19 Nov 2020 21:37:52 |
|                            | (b) (4)                  |                      |

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:14:36

[Vomiting](#)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)         | 19 Nov 2020 21:50:54 |
| User entered 'None (None)' | Samantha Wheeler (b) (4) | 19 Nov 2020 21:37:52 |
|                            | (b) (4)                  |                      |

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:14:36

[Diarrhea](#)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)         | 19 Nov 2020 21:50:54 |
| User entered 'None (None)' | Samantha Wheeler (b) (4) | 19 Nov 2020 21:37:52 |
|                            | (b) (4)                  |                      |

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:14:36

[Sore Throat](#)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)         | 19 Nov 2020 21:50:54 |
| User entered 'Mild (Mild)' | Samantha Wheeler (b) (4) | 19 Nov 2020 21:37:52 |
|                            | (b) (4)                  |                      |

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:14:36

[Symptom Day](#)

| Audit                        | User                     | Time (GMT)           |
|------------------------------|--------------------------|----------------------|
| User entered 'Day 3 (Day 3)' | Samantha Wheeler (b) (4) | 19 Nov 2020 21:39:24 |
|                              | (b) (4)                  |                      |



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Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:14:36

[Date](#)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)         | 19 Nov 2020 21:50:54 |
| User entered '07 Nov 2020' | Samantha Wheeler (b) (4) | 19 Nov 2020 21:39:24 |
|                            | (b) (4)                  |                      |

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:14:36

[Assessment Not Done](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 19 Nov 2020 21:50:54 |
| User entered '0'    | Samantha Wheeler (b) (4) | 19 Nov 2020 21:39:24 |
|                     | (b) (4)                  |                      |

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:14:36

[O2 Saturation](#)

| Audit                                    | User                     | Time (GMT)           |
|------------------------------------------|--------------------------|----------------------|
| DataPoint Verified.                      | (b) (4), (b) (6)         | 19 Nov 2020 21:50:54 |
| User entered missing code ND - Not Done. | Samantha Wheeler (b) (4) | 19 Nov 2020 21:39:24 |
|                                          | (b) (4)                  |                      |

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:14:36

[O2 Saturation Units](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '%' | System | 19 Nov 2020 21:39:24 |

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:14:36

[Temperature](#)

| Audit                                    | User                     | Time (GMT)           |
|------------------------------------------|--------------------------|----------------------|
| DataPoint Verified.                      | (b) (4), (b) (6)         | 19 Nov 2020 21:50:54 |
| User entered missing code ND - Not Done. | Samantha Wheeler (b) (4) | 19 Nov 2020 21:39:24 |
|                                          | (b) (4)                  |                      |

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:14:36

[Chills](#)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)         | 19 Nov 2020 21:50:54 |
| User entered 'None (None)' | Samantha Wheeler (b) (4) | 19 Nov 2020 21:39:24 |
|                            | (b) (4)                  |                      |

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:14:36

[Cough](#)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)         | 19 Nov 2020 21:50:54 |
| User entered 'None (None)' | Samantha Wheeler (b) (4) | 19 Nov 2020 21:39:24 |
|                            | (b) (4)                  |                      |

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:14:36

[Shortness of Breath](#)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)         | 19 Nov 2020 21:50:54 |
| User entered 'None (None)' | Samantha Wheeler (b) (4) | 19 Nov 2020 21:39:24 |
|                            | (b) (4)                  |                      |



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Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:14:36

[Difficulty Breathing](#)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)         | 19 Nov 2020 21:50:54 |
| User entered 'None (None)' | Samantha Wheeler (b) (4) | 19 Nov 2020 21:39:24 |
|                            | (b) (4)                  |                      |

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:14:36

[Fatigue](#)

| Audit                          | User                     | Time (GMT)           |
|--------------------------------|--------------------------|----------------------|
| DataPoint Verified.            | (b) (4), (b) (6)         | 19 Nov 2020 21:50:54 |
| User entered 'Severe (Severe)' | Samantha Wheeler (b) (4) | 19 Nov 2020 21:39:24 |
|                                | (b) (4)                  |                      |

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:14:36

[Muscle Aches \(Myalgia\)](#)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)         | 19 Nov 2020 21:50:54 |
| User entered 'None (None)' | Samantha Wheeler (b) (4) | 19 Nov 2020 21:39:24 |
|                            | (b) (4)                  |                      |

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:14:36

[Body Aches](#)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)         | 19 Nov 2020 21:50:54 |
| User entered 'None (None)' | Samantha Wheeler (b) (4) | 19 Nov 2020 21:39:24 |
|                            | (b) (4)                  |                      |

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:14:36

[Headache](#)

| Audit                          | User                     | Time (GMT)           |
|--------------------------------|--------------------------|----------------------|
| DataPoint Verified.            | (b) (4), (b) (6)         | 19 Nov 2020 21:50:54 |
| User entered 'Severe (Severe)' | Samantha Wheeler (b) (4) | 19 Nov 2020 21:39:24 |
|                                | (b) (4)                  |                      |

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:14:36

[New Loss of Taste](#)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)         | 19 Nov 2020 21:50:54 |
| User entered 'None (None)' | Samantha Wheeler (b) (4) | 19 Nov 2020 21:39:24 |
|                            | (b) (4)                  |                      |

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:14:36

[New Loss of Smell](#)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)         | 19 Nov 2020 21:50:54 |
| User entered 'None (None)' | Samantha Wheeler (b) (4) | 19 Nov 2020 21:39:24 |
|                            | (b) (4)                  |                      |

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:14:36

[Nasal Congestion](#)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)         | 19 Nov 2020 21:50:54 |
| User entered 'None (None)' | Samantha Wheeler (b) (4) | 19 Nov 2020 21:39:24 |
|                            | (b) (4)                  |                      |



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Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:14:36

[Runny Nose \(Rhinorrhea\)](#)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)         | 19 Nov 2020 21:50:54 |
| User entered 'None (None)' | Samantha Wheeler (b) (4) | 19 Nov 2020 21:39:24 |
|                            | (b) (4)                  |                      |

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:14:36

[Nausea](#)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)         | 19 Nov 2020 21:50:54 |
| User entered 'None (None)' | Samantha Wheeler (b) (4) | 19 Nov 2020 21:39:24 |
|                            | (b) (4)                  |                      |

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:14:36

[Vomiting](#)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)         | 19 Nov 2020 21:50:54 |
| User entered 'None (None)' | Samantha Wheeler (b) (4) | 19 Nov 2020 21:39:24 |
|                            | (b) (4)                  |                      |

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:14:36

[Diarrhea](#)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)         | 19 Nov 2020 21:50:54 |
| User entered 'None (None)' | Samantha Wheeler (b) (4) | 19 Nov 2020 21:39:24 |
|                            | (b) (4)                  |                      |

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:14:36

[Sore Throat](#)

| Audit                              | User                     | Time (GMT)           |
|------------------------------------|--------------------------|----------------------|
| DataPoint Verified.                | (b) (4), (b) (6)         | 19 Nov 2020 21:50:54 |
| User entered 'Moderate (Moderate)' | Samantha Wheeler (b) (4) | 19 Nov 2020 21:39:24 |
|                                    | (b) (4)                  |                      |

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:14:36

[Symptom Day](#)

| Audit                        | User                     | Time (GMT)           |
|------------------------------|--------------------------|----------------------|
| User entered 'Day 4 (Day 4)' | Samantha Wheeler (b) (4) | 19 Nov 2020 21:41:27 |
|                              | (b) (4)                  |                      |

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:14:36

[Date](#)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)         | 19 Nov 2020 21:50:54 |
| User entered '08 Nov 2020' | Samantha Wheeler (b) (4) | 19 Nov 2020 21:41:27 |
|                            | (b) (4)                  |                      |

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:14:36

[Assessment Not Done](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 19 Nov 2020 21:50:54 |
| User entered '0'    | Samantha Wheeler (b) (4) | 19 Nov 2020 21:41:27 |
|                     | (b) (4)                  |                      |



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Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:14:36

[O2 Saturation](#)

| Audit                                    | User                     | Time (GMT)           |
|------------------------------------------|--------------------------|----------------------|
| DataPoint Verified.                      | (b) (4), (b) (6)         | 19 Nov 2020 21:50:54 |
| User entered missing code ND - Not Done. | Samantha Wheeler (b) (4) | 19 Nov 2020 21:41:27 |
|                                          | (b) (4)                  |                      |

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:14:36

[O2 Saturation Units](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '%' | System | 19 Nov 2020 21:41:27 |

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:14:36

[Temperature](#)

| Audit                                    | User                     | Time (GMT)           |
|------------------------------------------|--------------------------|----------------------|
| DataPoint Verified.                      | (b) (4), (b) (6)         | 19 Nov 2020 21:50:54 |
| User entered missing code ND - Not Done. | Samantha Wheeler (b) (4) | 19 Nov 2020 21:41:27 |
|                                          | (b) (4)                  |                      |

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:14:36

[Chills](#)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)         | 19 Nov 2020 21:50:54 |
| User entered 'None (None)' | Samantha Wheeler (b) (4) | 19 Nov 2020 21:41:27 |
|                            | (b) (4)                  |                      |

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:14:36

[Cough](#)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)         | 19 Nov 2020 21:50:54 |
| User entered 'None (None)' | Samantha Wheeler (b) (4) | 19 Nov 2020 21:41:27 |
|                            | (b) (4)                  |                      |

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:14:36

[Shortness of Breath](#)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)         | 19 Nov 2020 21:50:54 |
| User entered 'None (None)' | Samantha Wheeler (b) (4) | 19 Nov 2020 21:41:27 |
|                            | (b) (4)                  |                      |

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:14:36

[Difficulty Breathing](#)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)         | 19 Nov 2020 21:50:54 |
| User entered 'None (None)' | Samantha Wheeler (b) (4) | 19 Nov 2020 21:41:27 |
|                            | (b) (4)                  |                      |

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:14:36

[Fatigue](#)

| Audit                              | User                     | Time (GMT)           |
|------------------------------------|--------------------------|----------------------|
| DataPoint Verified.                | (b) (4), (b) (6)         | 19 Nov 2020 21:50:54 |
| User entered 'Moderate (Moderate)' | Samantha Wheeler (b) (4) | 19 Nov 2020 21:41:27 |
|                                    | (b) (4)                  |                      |



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Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:14:36

[Muscle Aches \(Myalgia\)](#)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)         | 19 Nov 2020 21:50:54 |
| User entered 'None (None)' | Samantha Wheeler (b) (4) | 19 Nov 2020 21:41:27 |
|                            | (b) (4)                  |                      |

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:14:36

[Body Aches](#)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)         | 19 Nov 2020 21:50:54 |
| User entered 'None (None)' | Samantha Wheeler (b) (4) | 19 Nov 2020 21:41:27 |
|                            | (b) (4)                  |                      |

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:14:36

[Headache](#)

| Audit                          | User                     | Time (GMT)           |
|--------------------------------|--------------------------|----------------------|
| DataPoint Verified.            | (b) (4), (b) (6)         | 19 Nov 2020 21:50:54 |
| User entered 'Severe (Severe)' | Samantha Wheeler (b) (4) | 19 Nov 2020 21:41:27 |
|                                | (b) (4)                  |                      |

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:14:36

[New Loss of Taste](#)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)         | 19 Nov 2020 21:50:54 |
| User entered 'None (None)' | Samantha Wheeler (b) (4) | 19 Nov 2020 21:41:27 |
|                            | (b) (4)                  |                      |

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:14:36

[New Loss of Smell](#)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)         | 19 Nov 2020 21:50:54 |
| User entered 'None (None)' | Samantha Wheeler (b) (4) | 19 Nov 2020 21:41:27 |
|                            | (b) (4)                  |                      |

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:14:36

[Nasal Congestion](#)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)         | 19 Nov 2020 21:50:54 |
| User entered 'None (None)' | Samantha Wheeler (b) (4) | 19 Nov 2020 21:41:27 |
|                            | (b) (4)                  |                      |

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:14:36

[Runny Nose \(Rhinorrhea\)](#)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)         | 19 Nov 2020 21:50:54 |
| User entered 'None (None)' | Samantha Wheeler (b) (4) | 19 Nov 2020 21:41:27 |
|                            | (b) (4)                  |                      |

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:14:36

[Nausea](#)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)         | 19 Nov 2020 21:50:54 |
| User entered 'None (None)' | Samantha Wheeler (b) (4) | 19 Nov 2020 21:41:27 |
|                            | (b) (4)                  |                      |



US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:14:36

[Vomiting](#)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)         | 19 Nov 2020 21:50:54 |
| User entered 'None (None)' | Samantha Wheeler (b) (4) | 19 Nov 2020 21:41:27 |
|                            | (b) (4)                  |                      |

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:14:36

[Diarrhea](#)

| Audit                              | User                     | Time (GMT)           |
|------------------------------------|--------------------------|----------------------|
| DataPoint Verified.                | (b) (4), (b) (6)         | 19 Nov 2020 21:50:54 |
| User entered 'Moderate (Moderate)' | Samantha Wheeler (b) (4) | 19 Nov 2020 21:41:27 |
|                                    | (b) (4)                  |                      |

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:14:36

[Sore Throat](#)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)         | 19 Nov 2020 21:50:54 |
| User entered 'None (None)' | Samantha Wheeler (b) (4) | 19 Nov 2020 21:41:27 |
|                            | (b) (4)                  |                      |

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 11:14:36

[Date of Visit](#)

| Audit                     | User             | Time (GMT)           |
|---------------------------|------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6) | 19 Nov 2020 18:04:49 |
| User entered '9 Nov 2020' | (b) (4), (b) (6) | 10 Nov 2020 21:35:35 |

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 11:14:36

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 19 Nov 2020 18:04:49 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 10 Nov 2020 21:35:35 |

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 11:14:36

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

| Audit                                                                                  | User             | Time (GMT)           |
|----------------------------------------------------------------------------------------|------------------|----------------------|
| DataPoint Verified.                                                                    | (b) (4), (b) (6) | 19 Nov 2020 18:04:49 |
| User closed query 'Data is required. Please complete.' (Site from System).             | System           | 10 Nov 2020 21:35:41 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System           | 10 Nov 2020 21:35:41 |
| User entered 'No (N)' reason for change: Data Entry Error                              | (b) (4), (b) (6) | 10 Nov 2020 21:35:41 |
| User opened query 'Data is required. Please complete.' (Site from System).             | System           | 10 Nov 2020 21:35:35 |
| User entered empty.                                                                    | (b) (4), (b) (6) | 10 Nov 2020 21:35:35 |

**US3762161**

**Folder: Covid-19 Assessment 09 Nov 2020**

**Form: COVID Diagnostic Test**

**Generated On: 26 Nov 2020 11:14:36**

[Date of Test](#)

| Audit                     | User             | Time (GMT)           |
|---------------------------|------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6) | 19 Nov 2020 18:04:49 |
| User entered '9 Nov 2020' | (b) (4), (b) (6) | 10 Nov 2020 21:35:35 |

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 11:14:36

[Type of Test Performed](#)

| Audit                                                    | User             | Time (GMT)           |
|----------------------------------------------------------|------------------|----------------------|
| DataPoint Verified.                                      | (b) (4), (b) (6) | 19 Nov 2020 18:04:49 |
| User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)' | (b) (4), (b) (6) | 10 Nov 2020 21:35:35 |



US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 11:14:36

[Other, specify](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 19 Nov 2020 18:04:49 |
| User entered empty. | (b) (4), (b) (6) | 10 Nov 2020 21:35:35 |

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 11:14:36

[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 19 Nov 2020 18:04:49 |
| User entered 'No (N)' | (b) (4), (b) (6) | 10 Nov 2020 21:35:35 |

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 11:14:36

[Lab/ Institution Test Performed](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 19 Nov 2020 18:04:49 |
| User entered empty. | (b) (4), (b) (6) | 10 Nov 2020 21:35:35 |

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 11:14:36

[CLIA Certified?](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 19 Nov 2020 18:04:49 |
| User entered empty. | (b) (4), (b) (6) | 10 Nov 2020 21:35:35 |

**US3762161**

**Folder: Covid-19 Assessment 09 Nov 2020**

**Form: COVID Diagnostic Test**

**Generated On: 26 Nov 2020 11:14:36**

[COVID-19 Positive \(CSA Programming Field Only\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '0' | System | 10 Nov 2020 21:35:41 |

US3762161

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 26 Nov 2020 11:14:36

[Visit](#)

| Audit                                       | User                     | Time (GMT)           |
|---------------------------------------------|--------------------------|----------------------|
| User accepted default value 'Day 3 (Day 3)' | Samantha Wheeler (b) (4) | 19 Nov 2020 21:31:33 |
|                                             | (b) (4)                  |                      |

US3762161

**Folder: Illness Visit (1)**

**Form: Saliva Collection (1)**

**Generated On: 26 Nov 2020 11:14:36**

[Was Saliva Collected?](#)

| Audit                                      | User                     | Time (GMT)           |
|--------------------------------------------|--------------------------|----------------------|
| User entered 'NA (COVID-19 Negative) (NA)' | Samantha Wheeler (b) (4) | 19 Nov 2020 21:31:33 |
|                                            | (b) (4)                  |                      |

US3762161

**Folder: Illness Visit (1)**

**Form: Saliva Collection (1)**

**Generated On: 26 Nov 2020 11:14:36**

[Date of Collection](#)

| Audit               | User                                | Time (GMT)           |
|---------------------|-------------------------------------|----------------------|
| User entered empty. | Samantha Wheeler (b) (4)<br>(b) (4) | 19 Nov 2020 21:31:33 |



US3762161

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 26 Nov 2020 11:14:36

[Visit](#)

| Audit                                       | User                     | Time (GMT)           |
|---------------------------------------------|--------------------------|----------------------|
| User accepted default value 'Day 5 (Day 5)' | Samantha Wheeler (b) (4) | 19 Nov 2020 21:31:33 |
|                                             | (b) (4)                  |                      |

US3762161

**Folder: Illness Visit (1)**

**Form: Saliva Collection (2)**

**Generated On: 26 Nov 2020 11:14:36**

[Was Saliva Collected?](#)

| Audit                                      | User                     | Time (GMT)           |
|--------------------------------------------|--------------------------|----------------------|
| User entered 'NA (COVID-19 Negative) (NA)' | Samantha Wheeler (b) (4) | 19 Nov 2020 21:31:33 |
|                                            | (b) (4)                  |                      |

US3762161

**Folder: Illness Visit (1)**

**Form: Saliva Collection (2)**

**Generated On: 26 Nov 2020 11:14:36**

[Date of Collection](#)

| Audit               | User                                | Time (GMT)           |
|---------------------|-------------------------------------|----------------------|
| User entered empty. | Samantha Wheeler (b) (4)<br>(b) (4) | 19 Nov 2020 21:31:33 |

US3762161

**Folder: Illness Visit (1)**

**Form: Saliva Collection (3)**

**Generated On: 26 Nov 2020 11:14:36**

[Visit](#)

| Audit                                       | User                     | Time (GMT)           |
|---------------------------------------------|--------------------------|----------------------|
| User accepted default value 'Day 7 (Day 7)' | Samantha Wheeler (b) (4) | 19 Nov 2020 21:31:33 |
|                                             | (b) (4)                  |                      |

US3762161

**Folder: Illness Visit (1)**

**Form: Saliva Collection (3)**

**Generated On: 26 Nov 2020 11:14:36**

[Was Saliva Collected?](#)

| Audit                                      | User                     | Time (GMT)           |
|--------------------------------------------|--------------------------|----------------------|
| User entered 'NA (COVID-19 Negative) (NA)' | Samantha Wheeler (b) (4) | 19 Nov 2020 21:31:33 |
|                                            | (b) (4)                  |                      |

US3762161

**Folder: Illness Visit (1)**

**Form: Saliva Collection (3)**

**Generated On: 26 Nov 2020 11:14:36**

[Date of Collection](#)

| Audit               | User                                | Time (GMT)           |
|---------------------|-------------------------------------|----------------------|
| User entered empty. | Samantha Wheeler (b) (4)<br>(b) (4) | 19 Nov 2020 21:31:33 |

US3762161

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 26 Nov 2020 11:14:36

[Visit](#)

| Audit                                       | User                     | Time (GMT)           |
|---------------------------------------------|--------------------------|----------------------|
| User accepted default value 'Day 9 (Day 9)' | Samantha Wheeler (b) (4) | 19 Nov 2020 21:31:33 |
|                                             | (b) (4)                  |                      |

US3762161

**Folder: Illness Visit (1)**

**Form: Saliva Collection (4)**

**Generated On: 26 Nov 2020 11:14:36**

[Was Saliva Collected?](#)

| Audit                                      | User                     | Time (GMT)           |
|--------------------------------------------|--------------------------|----------------------|
| User entered 'NA (COVID-19 Negative) (NA)' | Samantha Wheeler (b) (4) | 19 Nov 2020 21:31:33 |
|                                            | (b) (4)                  |                      |



US3762161

**Folder: Illness Visit (1)**

**Form: Saliva Collection (4)**

**Generated On: 26 Nov 2020 11:14:36**

[Date of Collection](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| User entered empty. | Samantha Wheeler (b) (4) | 19 Nov 2020 21:31:33 |
|                     | (b) (4)                  |                      |

US3762161

**Folder: Illness Visit (1)**

**Form: Saliva Collection (5)**

**Generated On: 26 Nov 2020 11:14:36**

[Visit](#)

| Audit                                         | User                                | Time (GMT)           |
|-----------------------------------------------|-------------------------------------|----------------------|
| User accepted default value 'Day 14 (Day 14)' | Samantha Wheeler (b) (4)<br>(b) (4) | 19 Nov 2020 21:31:33 |

US3762161

**Folder: Illness Visit (1)**

**Form: Saliva Collection (5)**

**Generated On: 26 Nov 2020 11:14:36**

[Was Saliva Collected?](#)

| Audit                                      | User                     | Time (GMT)           |
|--------------------------------------------|--------------------------|----------------------|
| User entered 'NA (COVID-19 Negative) (NA)' | Samantha Wheeler (b) (4) | 19 Nov 2020 21:31:33 |
|                                            | (b) (4)                  |                      |

US3762161

**Folder: Illness Visit (1)**

**Form: Saliva Collection (5)**

**Generated On: 26 Nov 2020 11:14:36**

[Date of Collection](#)

| Audit               | User                                | Time (GMT)           |
|---------------------|-------------------------------------|----------------------|
| User entered empty. | Samantha Wheeler (b) (4)<br>(b) (4) | 19 Nov 2020 21:31:33 |

US3762161

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 26 Nov 2020 11:14:36

[Visit](#)

| Audit                                         | User                     | Time (GMT)           |
|-----------------------------------------------|--------------------------|----------------------|
| User accepted default value 'Day 21 (Day 21)' | Samantha Wheeler (b) (4) | 19 Nov 2020 21:31:33 |
|                                               | (b) (4)                  |                      |

US3762161

**Folder: Illness Visit (1)**

**Form: Saliva Collection (6)**

**Generated On: 26 Nov 2020 11:14:36**

[Was Saliva Collected?](#)

| Audit                                      | User                     | Time (GMT)           |
|--------------------------------------------|--------------------------|----------------------|
| User entered 'NA (COVID-19 Negative) (NA)' | Samantha Wheeler (b) (4) | 19 Nov 2020 21:31:33 |
|                                            | (b) (4)                  |                      |

US3762161

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 26 Nov 2020 11:14:36

[Date of Collection](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| User entered empty. | Samantha Wheeler (b) (4) | 19 Nov 2020 21:31:33 |
|                     | (b) (4)                  |                      |

US3762161

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 26 Nov 2020 11:14:36

[Visit](#)

| Audit                                         | User                                | Time (GMT)           |
|-----------------------------------------------|-------------------------------------|----------------------|
| User accepted default value 'Day 28 (Day 28)' | Samantha Wheeler (b) (4)<br>(b) (4) | 19 Nov 2020 21:31:33 |



US3762161

**Folder: Illness Visit (1)**

**Form: Saliva Collection (7)**

**Generated On: 26 Nov 2020 11:14:36**

[Was Saliva Collected?](#)

| Audit                                      | User                     | Time (GMT)           |
|--------------------------------------------|--------------------------|----------------------|
| User entered 'NA (COVID-19 Negative) (NA)' | Samantha Wheeler (b) (4) | 19 Nov 2020 21:31:33 |
|                                            | (b) (4)                  |                      |

US3762161

**Folder: Illness Visit (1)**

**Form: Saliva Collection (7)**

**Generated On: 26 Nov 2020 11:14:36**

[Date of Collection](#)

| Audit               | User                                | Time (GMT)           |
|---------------------|-------------------------------------|----------------------|
| User entered empty. | Samantha Wheeler (b) (4)<br>(b) (4) | 19 Nov 2020 21:31:33 |

US3762161

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:14:36

[Was this visit performed?](#)

| Audit                  | User                     | Time (GMT)           |
|------------------------|--------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)         | 19 Nov 2020 21:51:13 |
| User entered 'Yes (Y)' | Samantha Wheeler (b) (4) | 19 Nov 2020 20:37:09 |
|                        | (b) (4)                  |                      |

US3762161

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:14:36

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

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)         | 19 Nov 2020 21:51:13 |
| User entered '09 Nov 2020' | Samantha Wheeler (b) (4) | 19 Nov 2020 20:37:09 |
|                            | (b) (4)                  |                      |

US3762161

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:14:36

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

| Audit                          | User                     | Time (GMT)           |
|--------------------------------|--------------------------|----------------------|
| DataPoint Verified.            | (b) (4), (b) (6)         | 19 Nov 2020 21:51:13 |
| User entered 'Clinic (Clinic)' | Samantha Wheeler (b) (4) | 19 Nov 2020 20:37:09 |
|                                | (b) (4)                  |                      |

**US3762161**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 26 Nov 2020 11:14:36**

[Folder OID](#)

| Audit                 | User   | Time (GMT)           |
|-----------------------|--------|----------------------|
| User entered 'SICKD1' | System | 19 Nov 2020 20:37:09 |

US3762161

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:14:36

[Were vital signs assessed?](#)

| Audit                  | User                     | Time (GMT)           |
|------------------------|--------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)         | 19 Nov 2020 22:02:27 |
| User entered 'Yes (Y)' | Samantha Wheeler (b) (4) | 19 Nov 2020 21:58:38 |
|                        | (b) (4)                  |                      |

US3762161

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:14:36

Date of assessment (*dd MMM yyyy*)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)         | 19 Nov 2020 22:02:27 |
| User entered '09 Nov 2020' | Samantha Wheeler (b) (4) | 19 Nov 2020 21:58:38 |
|                            | (b) (4)                  |                      |



US3762161

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:14:36

Time of assessment (00:00-23:59)

| Audit                | User                     | Time (GMT)           |
|----------------------|--------------------------|----------------------|
| DataPoint Verified.  | (b) (4), (b) (6)         | 19 Nov 2020 22:02:27 |
| User entered '14:30' | Samantha Wheeler (b) (4) | 19 Nov 2020 21:58:38 |
|                      | (b) (4)                  |                      |

US3762161

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 11:14:36**

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

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '09 Nov 2020 14:30' | System | 19 Nov 2020 21:58:38 |

US3762161

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:14:36

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

| Audit                                    | User                     | Time (GMT)           |
|------------------------------------------|--------------------------|----------------------|
| DataPoint Verified.                      | (b) (4), (b) (6)         | 19 Nov 2020 22:02:27 |
| User entered missing code ND - Not Done. | Samantha Wheeler (b) (4) | 19 Nov 2020 21:58:38 |
| DataPoint set to visible.                | (b) (4)<br>System        | 19 Nov 2020 20:37:09 |

US3762161

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:14:36

Weight (xxx.x)

| Audit                                    | User                     | Time (GMT)           |
|------------------------------------------|--------------------------|----------------------|
| DataPoint Verified.                      | (b) (4), (b) (6)         | 19 Nov 2020 22:02:27 |
| User entered missing code ND - Not Done. | Samantha Wheeler (b) (4) | 19 Nov 2020 21:58:38 |
| DataPoint set to visible.                | (b) (4)<br>System        | 19 Nov 2020 20:37:09 |

US3762161

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:14:36

Temperature (xxx.x)

| Audit                 | User                     | Time (GMT)           |
|-----------------------|--------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)         | 19 Nov 2020 22:02:27 |
| User entered '98.4' F | Samantha Wheeler (b) (4) | 19 Nov 2020 21:58:38 |
|                       | (b) (4)                  |                      |

US3762161

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:14:36

[Route of measurement](#)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)         | 19 Nov 2020 22:02:27 |
| User entered 'Oral (Oral)' | Samantha Wheeler (b) (4) | 19 Nov 2020 21:58:38 |
|                            | (b) (4)                  |                      |

US3762161

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:14:36

[If Other, specify](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 19 Nov 2020 22:02:27 |
| User entered empty. | Samantha Wheeler (b) (4) | 19 Nov 2020 21:58:38 |
|                     | (b) (4)                  |                      |

US3762161

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:14:36

[Pulse \(xxx\)](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 19 Nov 2020 22:02:27 |
| User entered '88'   | Samantha Wheeler (b) (4) | 19 Nov 2020 21:58:38 |
|                     | (b) (4)                  |                      |



**US3762161**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 11:14:36**

[Pulse units](#)

| Audit              | User   | Time (GMT)           |
|--------------------|--------|----------------------|
| User entered 'bpm' | System | 19 Nov 2020 21:58:38 |

US3762161

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:14:36

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

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 19 Nov 2020 22:02:27 |
| User entered '16'   | Samantha Wheeler (b) (4) | 19 Nov 2020 21:58:38 |
|                     | (b) (4)                  |                      |

US3762161

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 11:14:36**

[Respiratory Rate units](#)

| Audit                      | User   | Time (GMT)           |
|----------------------------|--------|----------------------|
| User entered 'breaths/min' | System | 19 Nov 2020 21:58:38 |

US3762161

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:14:36

Systolic Blood Pressure (xxx)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 19 Nov 2020 22:02:27 |
| User entered '137'  | Samantha Wheeler (b) (4) | 19 Nov 2020 21:58:38 |
|                     | (b) (4)                  |                      |

US3762161

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 11:14:36**

[Systolic Blood Pressure units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 19 Nov 2020 21:58:38 |

US3762161

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:14:36

Diastolic Blood Pressure (xxx)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 19 Nov 2020 22:02:27 |
| User entered '78'   | Samantha Wheeler (b) (4) | 19 Nov 2020 21:58:38 |
|                     | (b) (4)                  |                      |

US3762161

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 11:14:36**

[Diastolic Blood Pressure units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 19 Nov 2020 21:58:38 |

US3762161

**Folder: Illness Visit Day 1 (1)**

**Form: Physical Examination**

**Generated On: 26 Nov 2020 11:14:36**

[Was the physical examination performed?](#)

| Audit                  | User                     | Time (GMT)           |
|------------------------|--------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)         | 19 Nov 2020 22:02:48 |
| User entered 'Yes (Y)' | Samantha Wheeler (b) (4) | 19 Nov 2020 21:58:59 |
|                        | (b) (4)                  |                      |



US3762161

**Folder: Illness Visit Day 1 (1)**

**Form: Physical Examination**

**Generated On: 26 Nov 2020 11:14:36**

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

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)         | 19 Nov 2020 22:02:48 |
| User entered '09 Nov 2020' | Samantha Wheeler (b) (4) | 19 Nov 2020 21:58:59 |
|                            | (b) (4)                  |                      |

US3762161

**Folder: Illness Visit Day 1 (1)**

**Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection**

**Generated On: 26 Nov 2020 11:14:36**

[Was Blood Sample Taken for Immunologic Assessment of SARS\\_COV-2 Infection?](#)

| Audit                  | User                     | Time (GMT)           |
|------------------------|--------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)         | 19 Nov 2020 22:02:59 |
| User entered 'Yes (Y)' | Samantha Wheeler (b) (4) | 19 Nov 2020 21:59:25 |
|                        | (b) (4)                  |                      |

US3762161

**Folder: Illness Visit Day 1 (1)**

**Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection**

**Generated On: 26 Nov 2020 11:14:36**

[Date of Collection](#)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)         | 19 Nov 2020 22:02:59 |
| User entered '09 Nov 2020' | Samantha Wheeler (b) (4) | 19 Nov 2020 21:59:25 |
|                            | (b) (4)                  |                      |

US3762161

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 11:14:36

[Did the participant experience any adverse events?](#)

| Audit                  | User                          | Time (GMT)           |
|------------------------|-------------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)              | 18 Nov 2020 14:34:10 |
| User entered 'Yes (Y)' | Kaitlyn Van Leuvan<br>(b) (4) | 11 Nov 2020 19:15:19 |

US3762161

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:14:36

[AEID](#)

| Audit                                                 | User             | Time (GMT)           |
|-------------------------------------------------------|------------------|----------------------|
| DataPoint Verified.                                   | (b) (4), (b) (6) | 17 Nov 2020 21:54:25 |
| Reviewed for Safety.                                  | (b) (4), (b) (6) | 12 Nov 2020 15:35:43 |
| User entered<br>'USA-US130-2020-mRNA-1273-P301000001' | System           | 12 Nov 2020 15:35:24 |
| User entered 'New'                                    | (b) (4), (b) (6) | 12 Nov 2020 15:35:24 |

US3762161

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:14:36

[Adverse event](#)

| Audit                                                                                                                                                                                                                                                                                                                                                         | User                                | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|----------------------|
| DataPoint Verified.                                                                                                                                                                                                                                                                                                                                           | (b) (4), (b) (6)                    | 17 Nov 2020 21:54:25 |
| User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Sepsis, bacteraemia, viraemia and fungaemia NEC, PT: Sepsis, LLT: Sepsis - version MedDRA\23.0.                                                                                                                                                      | Coder Import (b) (4)<br>(b) (4)     | 17 Nov 2020 20:41:50 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.                                                                                                                                                                                                                                                                   | Coder Import (b) (4)<br>(b) (4)     | 17 Nov 2020 20:41:50 |
| Data point term sent to Coder                                                                                                                                                                                                                                                                                                                                 | System                              | 17 Nov 2020 20:41:22 |
| Coding entries removed.                                                                                                                                                                                                                                                                                                                                       | Samantha Wheeler (b) (4)<br>(b) (4) | 17 Nov 2020 20:41:20 |
| User entered 'Sepsis' reason for change: Data Entry Error                                                                                                                                                                                                                                                                                                     | Samantha Wheeler (b) (4)<br>(b) (4) | 17 Nov 2020 20:41:20 |
| User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Sepsis, bacteraemia, viraemia and fungaemia NEC, PT: Intestinal sepsis, LLT: Intestinal sepsis - version MedDRA\23.0.                                                                                                                                | Coder Import (b) (4)<br>(b) (4)     | 16 Nov 2020 11:43:41 |
| User coded data point as Term Coded data point by User: (b) (6) version MedDRA\23.0.                                                                                                                                                                                                                                                                          | Coder Import (b) (4)<br>(b) (4)     | 16 Nov 2020 11:43:41 |
| Data point term sent to Coder                                                                                                                                                                                                                                                                                                                                 | System                              | 13 Nov 2020 19:51:43 |
| User closed query 'CDM Coding, please add to the text a unifying diagnosis. Alternatively split into separate records, as 'GASTROENTERITIS', 'SEPSIS', 'ACUTE KIDNEY INJURY' and 'POSSIBLE GI BLEED', reporting each event with all relevant information e.g. start and stop dates etc' (Site from System).                                                   | System                              | 13 Nov 2020 19:51:05 |
| Query 'CDM Coding, please add to the text a unifying diagnosis. Alternatively split into separate records, as 'GASTROENTERITIS', 'SEPSIS', 'ACUTE KIDNEY INJURY' and 'POSSIBLE GI BLEED', reporting each event with all relevant information e.g. start and stop dates etc' answered with 'Condition split into separate records updated' (Site from System). | (b) (4), (b) (6)                    | 13 Nov 2020 19:51:05 |
| User entered 'GASTROENTERITIS WITH SEPSIS' reason for change: Data Entry Error                                                                                                                                                                                                                                                                                | (b) (4), (b) (6)                    | 13 Nov 2020 19:50:42 |
| Data point term sent to Coder                                                                                                                                                                                                                                                                                                                                 | System                              | 13 Nov 2020 19:44:33 |

US3762161

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:14:36

[Adverse event](#)

| Audit                                                                                                                                                                                                                                                                                                       | User                       | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| User entered 'GASTROENTERITIS WITH SEPSIS, AND POSSIBLE GI BLEED.' reason for change: Data Entry Error                                                                                                                                                                                                      | (b) (4), (b) (6)           | 13 Nov 2020 19:44:07 |
| User opened query 'CDM Coding, please add to the text a unifying diagnosis. Alternatively split into separate records, as 'GASTROENTERITIS', 'SEPSIS', 'ACUTE KIDNEY INJURY' and 'POSSIBLE GI BLEED', reporting each event with all relevant information e.g. start and stop dates etc' (Site from System). | Coder Import (b) (4)       | 12 Nov 2020 03:30:40 |
| Data point term sent to Coder                                                                                                                                                                                                                                                                               | System                     | 11 Nov 2020 19:31:23 |
| User entered 'Gastroenteritis with sepsis, acute Kidney injury and possible GI Bleed.'                                                                                                                                                                                                                      | Kaitlyn Van Leuvan (b) (4) | 11 Nov 2020 19:31:23 |

US3762161

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:14:36

[Was this a medically-attended AE?](#)

| Audit                  | User                          | Time (GMT)           |
|------------------------|-------------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)              | 17 Nov 2020 21:54:25 |
| User entered 'Yes (Y)' | Kaitlyn Van Leuvan<br>(b) (4) | 11 Nov 2020 19:31:23 |



US3762161

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:14:36

[Was this a Solicited Adverse Reaction?](#)

| Audit                 | User                          | Time (GMT)           |
|-----------------------|-------------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)              | 17 Nov 2020 21:54:25 |
| User entered 'No (N)' | Kaitlyn Van Leuvan<br>(b) (4) | 11 Nov 2020 19:31:23 |

US3762161

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:14:36

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit                 | User                          | Time (GMT)           |
|-----------------------|-------------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)              | 17 Nov 2020 21:54:25 |
| User entered 'No (N)' | Kaitlyn Van Leuvan<br>(b) (4) | 11 Nov 2020 19:31:23 |

US3762161

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:14:36

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

| Audit                                                          | User                     | Time (GMT)           |
|----------------------------------------------------------------|--------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)         | 17 Nov 2020 21:54:25 |
| User entered '10 Nov 2020' reason for change: Data Entry Error | Samantha Wheeler (b) (4) | 17 Nov 2020 20:41:20 |
| User entered '09 Nov 2020'                                     | Kaitlyn Van Leuvan       | 11 Nov 2020 19:31:23 |

US3762161

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:14:36

Start time (00:00-23:59)

| Audit                                                                                                                                                                                        | User                       | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| DataPoint Verified.                                                                                                                                                                          | (b) (4), (b) (6)           | 17 Nov 2020 21:54:25 |
| User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).                                       | System                     | 17 Nov 2020 20:41:41 |
| User entered empty; reason for change Data Entry Error                                                                                                                                       | Samantha Wheeler (b) (4)   | 17 Nov 2020 20:41:41 |
| User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).                                       | System                     | 17 Nov 2020 20:41:20 |
| User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).                                       | (b) (4), (b) (6)           | 17 Nov 2020 05:45:03 |
| User closed query 'Data entered is non-conformant. Please correct.' (Site from System).                                                                                                      | System                     | 13 Nov 2020 19:40:25 |
| User entered '00:00' reason for change: Data Entry Error                                                                                                                                     | (b) (4), (b) (6)           | 13 Nov 2020 19:40:25 |
| Query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' answered with 'Start time is unknown per source ' (Site from System). | (b) (4), (b) (6)           | 13 Nov 2020 19:39:54 |
| User opened query 'Data entered is non-conformant. Please correct.' (Site from System).                                                                                                      | System                     | 13 Nov 2020 19:39:17 |
| User entered 'UN:UN' (non-conformant).                                                                                                                                                       | (b) (4), (b) (6)           | 13 Nov 2020 19:39:17 |
| User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).                                       | System                     | 11 Nov 2020 19:31:23 |
| User entered '00:00'                                                                                                                                                                         | Kaitlyn Van Leuvan (b) (4) | 11 Nov 2020 19:31:23 |

**US3762161**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 11:14:36**

[AE start date and time \(derived\)](#)

| Audit                                                 | User   | Time (GMT)           |
|-------------------------------------------------------|--------|----------------------|
| User entered empty.                                   | System | 17 Nov 2020 20:41:41 |
| User entered '10 Nov 2020 00:00'                      | System | 17 Nov 2020 20:41:20 |
| User entered '09 Nov 2020 00:00'                      | System | 13 Nov 2020 19:40:25 |
| User entered '09 Nov 2020 UN:UN'<br>(non-conformant). | System | 13 Nov 2020 19:39:17 |
| User entered '09 Nov 2020 00:00'                      | System | 11 Nov 2020 19:31:23 |

**US3762161**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 11:14:36**

[Ongoing?](#)

| Audit                  | User                          | Time (GMT)           |
|------------------------|-------------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)              | 17 Nov 2020 21:54:25 |
| User entered 'Yes (Y)' | Kaitlyn Van Leuvan<br>(b) (4) | 11 Nov 2020 19:31:23 |

US3762161

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:14:36

If not Ongoing, end date (dd MMM yyyy)

| Audit                                                                                                                                                                                                                                                     | User                       | Time (GMT)           |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Query 'PV Query: Please provide the event end date for sepsis, acute kidney injury, diarrhea, left upper lobe pneumonia and (diarrhea with) dehydration.' answered with 'i have provided all end dates for everything I am aware of.' (Site from Safety). | Samantha Wheeler (b) (4)   | 24 Nov 2020 19:21:24 |
| User opened query 'PV Query: Please provide the event end date for sepsis, acute kidney injury, diarrhea, left upper lobe pneumonia and (diarrhea with) dehydration.' (Site from Safety).                                                                 | (b) (4), (b) (6)           | 19 Nov 2020 22:43:20 |
| Query 'PV Query: Please provide the event end date ' canceled (Site from Safety).                                                                                                                                                                         | (b) (4), (b) (6)           | 19 Nov 2020 22:42:19 |
| User opened query 'PV Query: Please provide the event end date ' (Site from Safety).                                                                                                                                                                      | (b) (4), (b) (6)           | 19 Nov 2020 22:39:06 |
| DataPoint Verified.                                                                                                                                                                                                                                       | (b) (4), (b) (6)           | 17 Nov 2020 21:54:25 |
| User entered empty.                                                                                                                                                                                                                                       | Kaitlyn Van Leuvan (b) (4) | 11 Nov 2020 19:31:23 |

**US3762161**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 11:14:36**

[End time \(00:00-23:59\)](#)

| Audit               | User                          | Time (GMT)           |
|---------------------|-------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)              | 17 Nov 2020 21:54:25 |
| User entered empty. | Kaitlyn Van Leuvan<br>(b) (4) | 11 Nov 2020 19:31:23 |



**US3762161**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 11:14:36**

[AE End Date and Time \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 11 Nov 2020 19:31:23 |

**US3762161**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 11:14:36**

[Severity](#)

| Audit                                          | User                          | Time (GMT)           |
|------------------------------------------------|-------------------------------|----------------------|
| DataPoint Verified.                            | (b) (4), (b) (6)              | 17 Nov 2020 21:54:25 |
| User entered 'Grade 3/Severe (Grade 3/Severe)' | Kaitlyn Van Leuvan<br>(b) (4) | 11 Nov 2020 19:31:23 |

US3762161

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:14:36

[Is the adverse event serious?](#)

| Audit                  | User                          | Time (GMT)           |
|------------------------|-------------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)              | 17 Nov 2020 21:54:25 |
| User entered 'Yes (Y)' | Kaitlyn Van Leuvan<br>(b) (4) | 11 Nov 2020 19:31:23 |

**US3762161**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 11:14:36**

[Death](#)

| Audit               | User                          | Time (GMT)           |
|---------------------|-------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)              | 17 Nov 2020 21:54:25 |
| User entered '0'    | Kaitlyn Van Leuvan<br>(b) (4) | 11 Nov 2020 19:31:23 |

US3762161

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:14:36

[Life threatening](#)

| Audit               | User                          | Time (GMT)           |
|---------------------|-------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)              | 17 Nov 2020 21:54:25 |
| User entered '1'    | Kaitlyn Van Leuvan<br>(b) (4) | 11 Nov 2020 19:31:23 |

US3762161

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:14:36

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit                                                                                                                                                                                                                                                                     | User                          | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------|----------------------|
| DataPoint Verified.                                                                                                                                                                                                                                                       | (b) (4), (b) (6)              | 17 Nov 2020 21:54:25 |
| User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).                                 | (b) (4), (b) (6)              | 17 Nov 2020 05:45:28 |
| Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'Hospital admission updated ' (Site from System). | (b) (4), (b) (6)              | 13 Nov 2020 19:38:57 |
| User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).                                 | System                        | 11 Nov 2020 19:31:23 |
| User entered '1'                                                                                                                                                                                                                                                          | Kaitlyn Van Leuvan<br>(b) (4) | 11 Nov 2020 19:31:23 |

US3762161

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:14:36

Hospital Admission Date (*dd MMM yyyy*)

| Audit                      | User                          | Time (GMT)           |
|----------------------------|-------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)              | 17 Nov 2020 21:54:25 |
| User entered '10 Nov 2020' | Kaitlyn Van Leuvan<br>(b) (4) | 11 Nov 2020 19:31:23 |

US3762161

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:14:36

Hospital Discharge Date (dd MMM yyyy)

| Audit                                                                                                                                                                                                                                                                                                                              | User                       | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| DataPoint Verified.                                                                                                                                                                                                                                                                                                                | (b) (4), (b) (6)           | 24 Nov 2020 18:48:04 |
| Query 'PV Query: Hospital discharge date was reported as 15 Nov 2020 for events upper left lobe pneumonia, acute hyponatremia, hypokalemia, and (diarrhea with) dehydration. Please add the hospital discharge date for events sepsis, acute kidney injury, and diarrhea in the eCRF.' answered with 'updated' (Site from Safety). | Samantha Wheeler (b) (4)   | 24 Nov 2020 18:29:39 |
| DataPoint Un-verified.                                                                                                                                                                                                                                                                                                             | (b) (4)                    |                      |
| User entered '15 Nov 2020' reason for change: Data Entry Error                                                                                                                                                                                                                                                                     | Samantha Wheeler (b) (4)   | 24 Nov 2020 18:08:13 |
| User opened query 'PV Query: Hospital discharge date was reported as 15 Nov 2020 for events upper left lobe pneumonia, acute hyponatremia, hypokalemia, and (diarrhea with) dehydration. Please add the hospital discharge date for events sepsis, acute kidney injury, and diarrhea in the eCRF.' (Site from Safety).             | (b) (4), (b) (6)           | 19 Nov 2020 22:44:38 |
| DataPoint Verified.                                                                                                                                                                                                                                                                                                                | (b) (4), (b) (6)           | 17 Nov 2020 21:54:25 |
| User entered empty.                                                                                                                                                                                                                                                                                                                | Kaitlyn Van Leuvan (b) (4) | 11 Nov 2020 19:31:23 |



**US3762161**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 11:14:36**

[Admitted to ICU?](#)

| Audit                 | User                          | Time (GMT)           |
|-----------------------|-------------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)              | 17 Nov 2020 21:54:25 |
| User entered 'No (N)' | Kaitlyn Van Leuvan<br>(b) (4) | 11 Nov 2020 19:31:23 |

US3762161

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:14:36

[Number of Days in ICU](#)

| Audit               | User                          | Time (GMT)           |
|---------------------|-------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)              | 17 Nov 2020 21:54:25 |
| User entered empty. | Kaitlyn Van Leuvan<br>(b) (4) | 11 Nov 2020 19:31:23 |

US3762161

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:14:36

[Persistent or significant disability or incapacity](#)

| Audit               | User                          | Time (GMT)           |
|---------------------|-------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)              | 17 Nov 2020 21:54:25 |
| User entered '0'    | Kaitlyn Van Leuvan<br>(b) (4) | 11 Nov 2020 19:31:23 |

US3762161

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:14:36

[Congenital anomaly or birth defect](#)

| Audit               | User                          | Time (GMT)           |
|---------------------|-------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)              | 17 Nov 2020 21:54:25 |
| User entered '0'    | Kaitlyn Van Leuvan<br>(b) (4) | 11 Nov 2020 19:31:23 |

US3762161

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:14:36

[Other medically important event](#)

| Audit               | User                          | Time (GMT)           |
|---------------------|-------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)              | 17 Nov 2020 21:54:25 |
| User entered '0'    | Kaitlyn Van Leuvan<br>(b) (4) | 11 Nov 2020 19:31:23 |

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:14:36

[Relationship to investigational product](#)

| Audit                                    | User                          | Time (GMT)           |
|------------------------------------------|-------------------------------|----------------------|
| DataPoint Verified.                      | (b) (4), (b) (6)              | 17 Nov 2020 21:54:25 |
| User entered 'Not Related (NOT RELATED)' | Kaitlyn Van Leuvan<br>(b) (4) | 11 Nov 2020 19:31:23 |

US3762161

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:14:36

[Relationship to Study Procedure](#)

| Audit                                    | User                          | Time (GMT)           |
|------------------------------------------|-------------------------------|----------------------|
| DataPoint Verified.                      | (b) (4), (b) (6)              | 17 Nov 2020 21:54:25 |
| User entered 'Not Related (NOT RELATED)' | Kaitlyn Van Leuvan<br>(b) (4) | 11 Nov 2020 19:31:23 |

US3762161

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:14:36

Action taken with investigational product

| Audit                                                                                                                                                                                                                     | User                          | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------|----------------------|
| DataPoint Verified.                                                                                                                                                                                                       | (b) (4), (b) (6)              | 24 Nov 2020 18:48:04 |
| Query 'PV Query: As the last dose of study drug was given on 30 Sep 2020 , please update the action taken with study drug from none to not applicable.'<br>answered with 'Updated to not applicable ' (Site from Safety). | (b) (4), (b) (6)              | 24 Nov 2020 18:14:06 |
| DataPoint Un-verified.                                                                                                                                                                                                    | (b) (4), (b) (6)              | 24 Nov 2020 18:13:19 |
| User entered 'Not Applicable (NOT APPLICABLE)'<br>reason for change: Data Entry Error                                                                                                                                     | (b) (4), (b) (6)              | 24 Nov 2020 18:13:19 |
| User opened query 'PV Query: As the last dose of study drug was given on 30 Sep 2020 , please update the action taken with study drug from none to not applicable.' (Site from Safety).                                   | (b) (4), (b) (6)              | 19 Nov 2020 22:43:30 |
| Query 'PV Query: As the last dose of study drug was given on 30 Sep 2020 , please update the action taken with study drug from none to not applicable.'<br>canceled (Site from Safety).                                   | (b) (4), (b) (6)              | 19 Nov 2020 22:42:16 |
| User opened query 'PV Query: As the last dose of study drug was given on 30 Sep 2020 , please update the action taken with study drug from none to not applicable.' (Site from Safety).                                   | (b) (4), (b) (6)              | 19 Nov 2020 22:39:59 |
| DataPoint Verified.                                                                                                                                                                                                       | (b) (4), (b) (6)              | 17 Nov 2020 21:54:25 |
| User entered 'None (NONE)'                                                                                                                                                                                                | Kaitlyn Van Leuvan<br>(b) (4) | 11 Nov 2020 19:31:23 |



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Folder: Adverse Events

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[None](#)

| Audit               | User                          | Time (GMT)           |
|---------------------|-------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)              | 17 Nov 2020 21:54:25 |
| User entered '0'    | Kaitlyn Van Leuvan<br>(b) (4) | 11 Nov 2020 19:31:23 |

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:14:36

[Concomitant Medication](#)

| Audit               | User                          | Time (GMT)           |
|---------------------|-------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)              | 17 Nov 2020 21:54:25 |
| User entered '1'    | Kaitlyn Van Leuvan<br>(b) (4) | 11 Nov 2020 19:31:23 |

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:14:36

[Concomitant Procedure](#)

| Audit               | User                          | Time (GMT)           |
|---------------------|-------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)              | 17 Nov 2020 21:54:25 |
| User entered '0'    | Kaitlyn Van Leuvan<br>(b) (4) | 11 Nov 2020 19:31:23 |

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[Outcome](#)

| Audit                                                                                                                                                                                                                                                      | User                       | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Query 'PV Query: Please provide the final event outcome for events sepsis, acute kidney injury, diarrhea, left upper lobe pneumonia and (diarrhea with) dehydration.' answered with 'this is final at this time- no update on outcome' (Site from Safety). | Samantha Wheeler (b) (4)   | 24 Nov 2020 19:16:27 |
| User opened query 'PV Query: Please provide the final event outcome for events sepsis, acute kidney injury, diarrhea, left upper lobe pneumonia and (diarrhea with) dehydration.' (Site from Safety).                                                      | (b) (4), (b) (6)           | 19 Nov 2020 22:43:02 |
| Query 'PV Query: Please provide the final event outcome for event ' canceled (Site from Safety).                                                                                                                                                           | (b) (4), (b) (6)           | 19 Nov 2020 22:42:12 |
| User opened query 'PV Query: Please provide the final event outcome for event ' (Site from Safety).                                                                                                                                                        | (b) (4), (b) (6)           | 19 Nov 2020 22:38:51 |
| DataPoint Verified.                                                                                                                                                                                                                                        | (b) (4), (b) (6)           | 17 Nov 2020 21:54:25 |
| User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'                                                                                                                                                                                     | Kaitlyn Van Leuvan (b) (4) | 11 Nov 2020 19:31:23 |

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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

| Audit               | User                          | Time (GMT)           |
|---------------------|-------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)              | 17 Nov 2020 21:54:25 |
| User entered empty. | Kaitlyn Van Leuvan<br>(b) (4) | 11 Nov 2020 19:31:23 |

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Folder: Adverse Events

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[Narrative](#)

| Audit                                                                                                                                                                                                                                                                                                           | User                     | Time (GMT)           |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|----------------------|
| DataPoint Verified.                                                                                                                                                                                                                                                                                             | (b) (4), (b) (6)         | 24 Nov 2020 20:10:53 |
| Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' answered with 'will send.' (Site from Safety). | Samantha Wheeler (b) (4) | 24 Nov 2020 19:36:15 |
| Query 'PV Query: Please clarify if the sepsis was secondary to gastroenteritis or the reported pneumonia.' answered with 'sepsis is secondary to gastroenteritis.' (Site from Safety).                                                                                                                          | Samantha Wheeler (b) (4) | 24 Nov 2020 19:29:55 |
| Query 'PV Query: Please confirm if the subject experienced gastrointestinal bleed. If yes, please consider reported as separate AE/SAE.' answered with 'gastrointestinal bleed not noted on discharge summary' (Site from Safety).                                                                              | Samantha Wheeler (b) (4) | 24 Nov 2020 19:26:57 |
| Query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event.' answered with 'updated' (Site from Safety).                                                                                                                                                            | Samantha Wheeler (b) (4) | 24 Nov 2020 19:23:33 |
| DataPoint Un-verified.                                                                                                                                                                                                                                                                                          | Samantha Wheeler (b) (4) | 24 Nov 2020 19:23:00 |

US3762161

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:14:36

[Narrative](#)

| Audit                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | User                     | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|----------------------|
| User entered '74 Y/O MALE WHO RECEIVED SECOND DOSE OF PRODUCT ON 9/30 WITHOUT INCIDENT AND WAS SEEN FOR ROUTINE F/U ON 11/03 AND REPORTED NO SYMPTOMS WHO WAS ADMITTED TO WFBMC ON 11/10 WITH DIAGNOSIS OF GASTROENTERITIS WITH ASSOCIATED SEPSIS, ACUTE KIDNEY INJURY, AND POSSIBLE GI BLEED. HE HAD REPORTED FEELING TIRED WITH HEADACHES AND MUSCLE ACHES ON 11/09 AND WAS SEEN FOR A SICK VISIT. A PCR FOR COVID-19 WAS PERFORMED AT THE TIME WAS NEGATIVE. ON TELEPHONE F/U ON 11/10, HE REPORTED INCREASED FATIGUE AND DEVELOPMENT OF DIARRHEA WITH BLACK STOOL. WE RECOMMENDED GOING TO EDC (WHICH HAD ALSO BEEN RECOMMENDED BY PCP). HE WAS ADMITTED FROM THE ED AND DIAGNOSED AS ABOVE.<br /><br />patient does have underlying conditions such as diabetes, high cholesterol, hypertension, and CABG.' reason for change: Data Entry Error | Samantha Wheeler (b) (4) | 24 Nov 2020 19:23:00 |
| Query 'PV Query: Please provide treatment given for the events sepsis, acute kidney injury, diarrhea, acute hyponatremia, hypokalemia, and (diarrhea with) dehydration. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'all medications that were found within medical record have been reported in EDC' (Site from Safety).                                                                                                                                                                                                                                                                                                                                               | Samantha Wheeler (b) (4) | 24 Nov 2020 18:31:12 |
| Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'where will this information be reported?' (Site from Safety).                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | Samantha Wheeler (b) (4) | 24 Nov 2020 18:30:30 |
| User opened query 'PV Query: Please clarify if the sepsis was secondary to gastroenteritis or the reported pneumonia.' (Site from Safety).                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | (b) (4), (b) (6)         | 19 Nov 2020 22:45:10 |

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:14:36

[Narrative](#)

| Audit                                                                                                                                                                                                                                                                                                                                                                                                              | User             | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| User opened query 'PV Query: Please confirm if the subject experienced gastrointestinal bleed. If yes, please consider reported as separate AE/SAE.' (Site from Safety).                                                                                                                                                                                                                                           | (b) (4), (b) (6) | 19 Nov 2020 22:44:50 |
| User opened query 'PV Query: Please provide treatment given for the events sepsis, acute kidney injury, diarrhea, acute hyponatremia, hypokalemia, and (diarrhea with) dehydration. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety). | (b) (4), (b) (6) | 19 Nov 2020 22:44:15 |
| 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) | 19 Nov 2020 22:44:04 |
| User opened query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event.' (Site from Safety).                                                                                                                                                                                                                                                                           | (b) (4), (b) (6) | 19 Nov 2020 22:43:51 |
| User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).                                                                                                                   | (b) (4), (b) (6) | 19 Nov 2020 22:43:42 |
| Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' canceled (Site from Safety).                                                                                                                      | (b) (4), (b) (6) | 19 Nov 2020 22:42:08 |
| Query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event.' canceled (Site from Safety).                                                                                                                                                                                                                                                                              | (b) (4), (b) (6) | 19 Nov 2020 22:42:05 |
| Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' canceled (Site from Safety).                                                                                                                                                                                                                                        | (b) (4), (b) (6) | 19 Nov 2020 22:42:01 |
| 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) | 19 Nov 2020 22:41:07 |



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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

| Audit                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | User                          | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------|----------------------|
| User opened query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event.' (Site from Safety).                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | (b) (4), (b) (6)              | 19 Nov 2020 22:40:36 |
| User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).                                                                                                                                                                                                                                                                                                                                                                                                  | (b) (4), (b) (6)              | 19 Nov 2020 22:40:12 |
| DataPoint Verified.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | (b) (4), (b) (6)              | 17 Nov 2020 21:54:25 |
| User entered '74 y/o male who received second dose of product on 9/30 without incident and was seen for routine f/u on 11/03 and reported no symptoms who was admitted to WFBMC on 11/10 with diagnosis of gastroenteritis with associated sepsis, acute kidney injury, and possible GI bleed. He had reported feeling tired with headaches and muscle aches on 11/09 and was seen for a sick visit. A PCR for Covid-19 was performed at the time was negative. On telephone f/u on 11/10, he reported increased fatigue and development of diarrhea with black stool. We recommended going to EDC (which had also been recommended by PCP). He was admitted from the ED and diagnosed as above.' | Kaitlyn Van Leuvan<br>(b) (4) | 11 Nov 2020 19:31:23 |

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 11:14:36**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 11 Nov 2020 19:31:23 |

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**Folder:** Adverse Events

**Form:** Adverse Events (1)

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[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 11 Nov 2020 19:31:23 |

**US3762161**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 11:14:36**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '0' | System | 11 Nov 2020 19:31:23 |

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 26 Nov 2020 11:14:36**

[AEID](#)

| Audit                                                 | User             | Time (GMT)           |
|-------------------------------------------------------|------------------|----------------------|
| DataPoint Verified.                                   | (b) (4), (b) (6) | 17 Nov 2020 21:54:25 |
| Reviewed for Safety.                                  | (b) (4), (b) (6) | 16 Nov 2020 14:48:40 |
| User entered<br>'USA-US130-2020-mRNA-1273-P301000001' | (b) (4), (b) (6) | 16 Nov 2020 14:48:34 |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:14:36

[Adverse event](#)

| Audit                                                                                                                                                                                                              | User                 | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|----------------------|
| DataPoint Verified.                                                                                                                                                                                                | (b) (4), (b) (6)     | 17 Nov 2020 21:54:25 |
| User coded data point as SOC: Renal and urinary disorders, HLT: Renal disorders (excl nephropathies), HLT: Renal failure and impairment, PT: Acute kidney injury, LLT: Acute kidney injury - version MedDRA\\23.0. | Coder Import (b) (4) | 13 Nov 2020 19:46:51 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.                                                                                                                       | (b) (4)              | 13 Nov 2020 19:46:51 |
| Data point term sent to Coder                                                                                                                                                                                      | System               | 13 Nov 2020 19:45:34 |
| User entered 'ACUTE KIDNEY INJURY'                                                                                                                                                                                 | (b) (4), (b) (6)     | 13 Nov 2020 19:45:14 |

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 26 Nov 2020 11:14:36**

[Was this a medically-attended AE?](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 17 Nov 2020 21:54:25 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 13 Nov 2020 19:45:14 |

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Folder: Adverse Events

Form: Adverse Events (2)

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[Was this a Solicited Adverse Reaction?](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 17 Nov 2020 21:54:25 |
| User entered 'No (N)' | (b) (4), (b) (6) | 13 Nov 2020 19:45:14 |



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Folder: Adverse Events

Form: Adverse Events (2)

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[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 17 Nov 2020 21:54:25 |
| User entered 'No (N)' | (b) (4), (b) (6) | 13 Nov 2020 19:45:14 |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:14:36

Start date (dd MMM yyyy)

| Audit                                                          | User                     | Time (GMT)           |
|----------------------------------------------------------------|--------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)         | 17 Nov 2020 21:54:25 |
| User entered '10 Nov 2020' reason for change: Data Entry Error | Samantha Wheeler (b) (4) | 17 Nov 2020 20:42:10 |
| User entered '09 Nov 2020' reason for change: Data Entry Error | (b) (4)                  |                      |
|                                                                | (b) (4), (b) (6)         | 13 Nov 2020 19:47:28 |
| User entered '10 Nov 2020'                                     | (b) (4), (b) (6)         | 13 Nov 2020 19:45:14 |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:14:36

Start time (00:00-23:59)

| Audit                                                                                                                                                                             | User                     | Time (GMT)           |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|----------------------|
| DataPoint Verified.                                                                                                                                                               | (b) (4), (b) (6)         | 24 Nov 2020 18:48:04 |
| Query 'per CDM RQ: please remove data from this field' answered with 'Data has been removed' (Site from DM).                                                                      | (b) (4), (b) (6)         | 24 Nov 2020 18:16:53 |
| DataPoint Un-verified.                                                                                                                                                            | Samantha Wheeler (b) (4) | 19 Nov 2020 21:31:13 |
| User entered empty; reason for change Data Entry Error                                                                                                                            | Samantha Wheeler (b) (4) | 19 Nov 2020 21:31:13 |
| User opened query 'per CDM RQ: please remove data from this field' (Site from DM).                                                                                                | (b) (4), (b) (6)         | 19 Nov 2020 18:51:54 |
| User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).                            | (b) (4), (b) (6)         | 19 Nov 2020 17:27:00 |
| DataPoint Verified.                                                                                                                                                               | (b) (4), (b) (6)         | 17 Nov 2020 21:54:25 |
| Query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' answered with 'start time is unknown ' (Site from System). | (b) (4), (b) (6)         | 13 Nov 2020 19:47:38 |
| User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).                            | System                   | 13 Nov 2020 19:45:14 |
| User entered '00:00'                                                                                                                                                              | (b) (4), (b) (6)         | 13 Nov 2020 19:45:14 |

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Folder: Adverse Events

Form: Adverse Events (2)

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[AE start date and time \(derived\)](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered empty.              | System | 19 Nov 2020 21:31:13 |
| User entered '10 Nov 2020 00:00' | System | 17 Nov 2020 20:42:10 |
| User entered '09 Nov 2020 00:00' | System | 13 Nov 2020 19:47:28 |
| User entered '10 Nov 2020 00:00' | System | 13 Nov 2020 19:45:14 |

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Folder: Adverse Events

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[Ongoing?](#)

| Audit                                                     | User                     | Time (GMT)           |
|-----------------------------------------------------------|--------------------------|----------------------|
| DataPoint Verified.                                       | (b) (4), (b) (6)         | 24 Nov 2020 19:18:16 |
| DataPoint Un-verified.                                    | Samantha Wheeler (b) (4) | 24 Nov 2020 19:16:57 |
| User entered 'No (N)' reason for change: Data Entry Error | (b) (4)                  | 24 Nov 2020 19:16:57 |
| DataPoint Verified.                                       | (b) (4), (b) (6)         | 17 Nov 2020 21:54:25 |
| User entered 'Yes (Y)'                                    | (b) (4), (b) (6)         | 13 Nov 2020 19:45:14 |

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If not Ongoing, end date (dd MMM yyyy)

| Audit                                                                                                                                                                       | User                     | Time (GMT)           |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|----------------------|
| User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).             | System                   | 24 Nov 2020 19:20:52 |
| Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System). | System                   | 24 Nov 2020 19:20:52 |
| DataPoint Verified.                                                                                                                                                         | (b) (4), (b) (6)         | 24 Nov 2020 19:18:16 |
| User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).             | System                   | 24 Nov 2020 19:16:57 |
| DataPoint Un-verified.                                                                                                                                                      | Samantha Wheeler (b) (4) | 24 Nov 2020 19:16:57 |
| User entered '11 Nov 2020' reason for change: Data Entry Error                                                                                                              | (b) (4)                  | 24 Nov 2020 19:16:57 |
| DataPoint Verified.                                                                                                                                                         | (b) (4)                  | 24 Nov 2020 19:16:57 |
|                                                                                                                                                                             | (b) (4), (b) (6)         | 17 Nov 2020 21:54:25 |
| User entered empty.                                                                                                                                                         | (b) (4), (b) (6)         | 13 Nov 2020 19:45:14 |

US3762161

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:14:36

[End time \(00:00-23:59\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 17 Nov 2020 21:54:25 |
| User entered empty. | (b) (4), (b) (6) | 13 Nov 2020 19:45:14 |

**US3762161**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 26 Nov 2020 11:14:36**

[AE End Date and Time \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 13 Nov 2020 19:45:14 |



**US3762161**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 26 Nov 2020 11:14:36**

[Severity](#)

| Audit                                          | User             | Time (GMT)           |
|------------------------------------------------|------------------|----------------------|
| DataPoint Verified.                            | (b) (4), (b) (6) | 17 Nov 2020 21:54:25 |
| User entered 'Grade 3/Severe (Grade 3/Severe)' | (b) (4), (b) (6) | 13 Nov 2020 19:45:14 |

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Folder: Adverse Events

Form: Adverse Events (2)

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[Is the adverse event serious?](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 17 Nov 2020 21:54:25 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 13 Nov 2020 19:45:14 |

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 26 Nov 2020 11:14:36**

[Death](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 17 Nov 2020 21:54:25 |
| User entered '0'    | (b) (4), (b) (6) | 13 Nov 2020 19:45:14 |

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Folder: Adverse Events

Form: Adverse Events (2)

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[Life threatening](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 17 Nov 2020 21:54:25 |
| User entered '1'    | (b) (4), (b) (6) | 13 Nov 2020 19:45:14 |

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Folder: Adverse Events

Form: Adverse Events (2)

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[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit                                                                                                                                                                                                                                                                         | User             | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).<br>DataPoint Verified.              | (b) (4), (b) (6) | 19 Nov 2020 17:22:37 |
|                                                                                                                                                                                                                                                                               | (b) (4), (b) (6) | 17 Nov 2020 21:54:25 |
| Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'Hospital admission date updated' (Site from System). | (b) (4), (b) (6) | 13 Nov 2020 19:46:49 |
| User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).                                     | System           | 13 Nov 2020 19:45:14 |
| User entered '1'                                                                                                                                                                                                                                                              | (b) (4), (b) (6) | 13 Nov 2020 19:45:14 |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:14:36

Hospital Admission Date (*dd MMM yyyy*)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 17 Nov 2020 21:54:25 |
| User entered '10 Nov 2020' | (b) (4), (b) (6) | 13 Nov 2020 19:45:14 |

US3762161

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:14:36

[Hospital Discharge Date \(dd MMM yyyy\)](#)

| Audit                                                          | User             | Time (GMT)           |
|----------------------------------------------------------------|------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6) | 24 Nov 2020 18:48:04 |
| DataPoint Un-verified.                                         | (b) (4), (b) (6) | 24 Nov 2020 18:17:20 |
| User entered '15 Nov 2020' reason for change: Data Entry Error | (b) (4), (b) (6) | 24 Nov 2020 18:17:20 |
| DataPoint Verified.                                            | (b) (4), (b) (6) | 17 Nov 2020 21:54:25 |
| User entered empty.                                            | (b) (4), (b) (6) | 13 Nov 2020 19:45:14 |

**US3762161**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 26 Nov 2020 11:14:36**

[Admitted to ICU?](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 17 Nov 2020 21:54:25 |
| User entered 'No (N)' | (b) (4), (b) (6) | 13 Nov 2020 19:45:14 |



US3762161

**Folder:** Adverse Events

**Form:** Adverse Events (2)

**Generated On:** 26 Nov 2020 11:14:36

[Number of Days in ICU](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 17 Nov 2020 21:54:25 |
| User entered empty. | (b) (4), (b) (6) | 13 Nov 2020 19:45:14 |

US3762161

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:14:36

[Persistent or significant disability or incapacity](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 17 Nov 2020 21:54:25 |
| User entered '0'    | (b) (4), (b) (6) | 13 Nov 2020 19:45:14 |

US3762161

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:14:36

[Congenital anomaly or birth defect](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 17 Nov 2020 21:54:25 |
| User entered '0'    | (b) (4), (b) (6) | 13 Nov 2020 19:45:14 |

US3762161

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:14:36

[Other medically important event](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 17 Nov 2020 21:54:25 |
| User entered '0'    | (b) (4), (b) (6) | 13 Nov 2020 19:45:14 |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:14:36

[Relationship to investigational product](#)

| Audit                                                                                  | User             | Time (GMT)           |
|----------------------------------------------------------------------------------------|------------------|----------------------|
| DataPoint Verified.                                                                    | (b) (4), (b) (6) | 17 Nov 2020 21:54:25 |
| User closed query 'Data is required. Please complete.' (Site from System).             | System           | 13 Nov 2020 19:47:28 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System           | 13 Nov 2020 19:47:28 |
| User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error           | (b) (4), (b) (6) | 13 Nov 2020 19:47:28 |
| User opened query 'Data is required. Please complete.' (Site from System).             | System           | 13 Nov 2020 19:45:14 |
| User entered empty.                                                                    | (b) (4), (b) (6) | 13 Nov 2020 19:45:14 |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:14:36

[Relationship to Study Procedure](#)

| Audit                                                                                  | User             | Time (GMT)           |
|----------------------------------------------------------------------------------------|------------------|----------------------|
| DataPoint Verified.                                                                    | (b) (4), (b) (6) | 17 Nov 2020 21:54:25 |
| User closed query 'Data is required. Please complete.' (Site from System).             | System           | 13 Nov 2020 19:47:28 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System           | 13 Nov 2020 19:47:28 |
| User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error           | (b) (4), (b) (6) | 13 Nov 2020 19:47:28 |
| User opened query 'Data is required. Please complete.' (Site from System).             | System           | 13 Nov 2020 19:45:14 |
| User entered empty.                                                                    | (b) (4), (b) (6) | 13 Nov 2020 19:45:14 |

US3762161

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:14:36

[Action taken with investigational product](#)

| Audit                                                                                  | User             | Time (GMT)           |
|----------------------------------------------------------------------------------------|------------------|----------------------|
| DataPoint Verified.                                                                    | (b) (4), (b) (6) | 24 Nov 2020 18:48:04 |
| DataPoint Un-verified.                                                                 | (b) (4), (b) (6) | 24 Nov 2020 18:17:38 |
| User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error     | (b) (4), (b) (6) | 24 Nov 2020 18:17:38 |
| DataPoint Verified.                                                                    | (b) (4), (b) (6) | 17 Nov 2020 21:54:25 |
| User closed query 'Data is required. Please complete.' (Site from System).             | System           | 13 Nov 2020 19:47:28 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System           | 13 Nov 2020 19:47:28 |
| User entered 'None (NONE)' reason for change: Data Entry Error                         | (b) (4), (b) (6) | 13 Nov 2020 19:47:28 |
| User opened query 'Data is required. Please complete.' (Site from System).             | System           | 13 Nov 2020 19:45:14 |
| User entered empty.                                                                    | (b) (4), (b) (6) | 13 Nov 2020 19:45:14 |

US3762161

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:14:36

[None](#)

| Audit                                                                                                                              | User             | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| DataPoint Verified.                                                                                                                | (b) (4), (b) (6) | 17 Nov 2020 21:54:25 |
| User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System). | System           | 13 Nov 2020 19:47:28 |
| User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System). | System           | 13 Nov 2020 19:45:14 |
| User entered '0'                                                                                                                   | (b) (4), (b) (6) | 13 Nov 2020 19:45:14 |



US3762161

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:14:36

[Concomitant Medication](#)

| Audit                                                | User             | Time (GMT)           |
|------------------------------------------------------|------------------|----------------------|
| DataPoint Verified.                                  | (b) (4), (b) (6) | 17 Nov 2020 21:54:25 |
| User entered '1' reason for change: Data Entry Error | (b) (4), (b) (6) | 13 Nov 2020 19:47:28 |
| User entered '0'                                     | (b) (4), (b) (6) | 13 Nov 2020 19:45:14 |

US3762161

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:14:36

[Concomitant Procedure](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 17 Nov 2020 21:54:25 |
| User entered '0'    | (b) (4), (b) (6) | 13 Nov 2020 19:45:14 |

US3762161

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:14:36

[Outcome](#)

| Audit                                                                                                      | User                     | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------|--------------------------|----------------------|
| DataPoint Verified.                                                                                        | (b) (4), (b) (6)         | 24 Nov 2020 20:10:53 |
| DataPoint Un-verified.                                                                                     | Samantha Wheeler (b) (4) | 24 Nov 2020 19:20:52 |
| User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:                                  | (b) (4)                  |                      |
| Data Entry Error                                                                                           | Samantha Wheeler (b) (4) | 24 Nov 2020 19:20:52 |
| DataPoint Verified.                                                                                        | (b) (4), (b) (6)         | 17 Nov 2020 21:54:25 |
| User closed query 'Data is required. Please complete.' (Site from System).                                 | System                   | 13 Nov 2020 19:47:28 |
| Query 'Data is required. Please complete.' answered by data change (Site from System).                     | System                   | 13 Nov 2020 19:47:28 |
| User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: Data Entry Error | (b) (4), (b) (6)         | 13 Nov 2020 19:47:28 |
| User opened query 'Data is required. Please complete.' (Site from System).                                 | System                   | 13 Nov 2020 19:45:14 |
| User entered empty.                                                                                        | (b) (4), (b) (6)         | 13 Nov 2020 19:45:14 |

**US3762161**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 26 Nov 2020 11:14:36**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 17 Nov 2020 21:54:25 |
| User entered empty. | (b) (4), (b) (6) | 13 Nov 2020 19:45:14 |

US3762161

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:14:36

[Narrative](#)

| Audit                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | User                     | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|----------------------|
| DataPoint Verified.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | (b) (4), (b) (6)         | 24 Nov 2020 20:26:41 |
| DataPoint Un-verified.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | Samantha Wheeler (b) (4) | 24 Nov 2020 20:20:07 |
| User entered '74 Y/O MALE WHO RECEIVED SECOND DOSE OF PRODUCT ON 9/30 WITHOUT INCIDENT AND WAS SEEN FOR ROUTINE F/U ON 11/03 AND REPORTED NO SYMPTOMS WHO WAS ADMITTED TO WFBMC ON 11/10 WITH DIAGNOSIS OF GASTROENTERITIS WITH ASSOCIATED SEPSIS, ACUTE KIDNEY INJURY, AND POSSIBLE GI BLEED. HE HAD REPORTED FEELING TIRED WITH HEADACHES AND MUSCLE ACHES ON 11/09 AND WAS SEEN FOR A SICK VISIT. A PCR FOR COVID-19 WAS PERFORMED AT THE TIME WAS NEGATIVE. ON TELEPHONE F/U ON 11/10, HE REPORTED INCREASED FATIGUE AND DEVELOPMENT OF DIARRHEA WITH BLACK STOOL. WE RECOMMENDED GOING TO EDC (WHICH HAD ALSO BEEN RECOMMENDED BY PCP). HE WAS ADMITTED FROM THE ED AND DIAGNOSED AS ABOVE. | Samantha Wheeler (b) (4) | 24 Nov 2020 20:20:07 |
| Creatinine:<br>11/10/20 17:59= 1.75<br>11/11/20 06:41= 1.32<br>11/12/07:02= 1.41<br>11/13/20 06:15= 1.53<br>11/14/20 08:01= 1.41' reason for change: Data Entry Error                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                          |                      |
| DataPoint Verified.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | (b) (4), (b) (6)         | 17 Nov 2020 21:54:25 |
| User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | System                   | 13 Nov 2020 19:46:28 |
| Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | System                   | 13 Nov 2020 19:46:28 |

US3762161

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:14:36

[Narrative](#)

| Audit                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | User             | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| User entered '74 Y/O MALE WHO RECEIVED SECOND DOSE OF PRODUCT ON 9/30 WITHOUT INCIDENT AND WAS SEEN FOR ROUTINE F/U ON 11/03 AND REPORTED NO SYMPTOMS WHO WAS ADMITTED TO WFBMC ON 11/10 WITH DIAGNOSIS OF GASTROENTERITIS WITH ASSOCIATED SEPSIS, ACUTE KIDNEY INJURY, AND POSSIBLE GI BLEED. HE HAD REPORTED FEELING TIRED WITH HEADACHES AND MUSCLE ACHES ON 11/09 AND WAS SEEN FOR A SICK VISIT. A PCR FOR COVID-19 WAS PERFORMED AT THE TIME WAS NEGATIVE. ON TELEPHONE F/U ON 11/10, HE REPORTED INCREASED FATIGUE AND DEVELOPMENT OF DIARRHEA WITH BLACK STOOL. WE RECOMMENDED GOING TO EDC (WHICH HAD ALSO BEEN RECOMMENDED BY PCP). HE WAS ADMITTED FROM THE ED AND DIAGNOSED AS ABOVE.' reason for change: Data Entry Error | (b) (4), (b) (6) | 13 Nov 2020 19:46:28 |
| User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | System           | 13 Nov 2020 19:45:14 |
| User entered empty.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | (b) (4), (b) (6) | 13 Nov 2020 19:45:14 |

**US3762161**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 26 Nov 2020 11:14:36**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 13 Nov 2020 19:45:14 |

**US3762161**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 26 Nov 2020 11:14:36**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 13 Nov 2020 19:45:14 |



**US3762161**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 26 Nov 2020 11:14:36**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '0' | System | 13 Nov 2020 19:45:14 |

**US3762161**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 26 Nov 2020 11:14:36**

[AEID](#)

| Audit                                                 | User             | Time (GMT)           |
|-------------------------------------------------------|------------------|----------------------|
| DataPoint Verified.                                   | (b) (4), (b) (6) | 17 Nov 2020 21:54:25 |
| Reviewed for Safety.                                  | (b) (4), (b) (6) | 16 Nov 2020 14:49:18 |
| User entered<br>'USA-US130-2020-mRNA-1273-P301000001' | (b) (4), (b) (6) | 16 Nov 2020 14:49:13 |

US3762161

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:14:36

[Adverse event](#)

| Audit                                                                                                                                                                                                                           | User                     | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|----------------------|
| DataPoint Verified.                                                                                                                                                                                                             | (b) (4), (b) (6)         | 19 Nov 2020 18:05:46 |
| User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Diarrhoea (excl infective), PT: Diarrhoea, LLT: Diarrhea - version MedDRA\23.0.                      | Coder Import (b) (4)     | 18 Nov 2020 14:33:06 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.                                                                                                                                     | (b) (4)                  | 18 Nov 2020 14:33:06 |
| Data point term sent to Coder                                                                                                                                                                                                   | System                   | 18 Nov 2020 14:32:03 |
| User closed query 'For coding purposes, please split DIARRHEA WITH DEHYDRATION into separate entries. 1. DIARRHEA and 2. [DIARRHEA WITH] DEHYDRATION' (Site from System).                                                       | System                   | 18 Nov 2020 14:32:02 |
| Query 'For coding purposes, please split DIARRHEA WITH DEHYDRATION into separate entries. 1. DIARRHEA and 2. [DIARRHEA WITH] DEHYDRATION' answered with 'seperated' (Site from System).                                         | Samantha Wheeler (b) (4) | 18 Nov 2020 14:32:02 |
| User entered 'DIARRHEA' reason for change: Data Entry Error                                                                                                                                                                     | (b) (4)                  | 18 Nov 2020 14:31:52 |
| User opened query 'For coding purposes, please split DIARRHEA WITH DEHYDRATION into separate entries. 1. DIARRHEA and 2. [DIARRHEA WITH] DEHYDRATION' (Site from System).                                                       | Coder Import (b) (4)     | 18 Nov 2020 14:30:05 |
| Data point term sent to Coder                                                                                                                                                                                                   | System                   | 18 Nov 2020 14:20:55 |
| DataPoint Un-verified.                                                                                                                                                                                                          | Samantha Wheeler (b) (4) | 18 Nov 2020 14:20:18 |
| Coding entries removed.                                                                                                                                                                                                         | (b) (4)                  |                      |
|                                                                                                                                                                                                                                 | Samantha Wheeler (b) (4) | 18 Nov 2020 14:20:18 |
| User entered 'diarrhea with dehydration' reason for change: Data Entry Error                                                                                                                                                    | (b) (4)                  |                      |
| DataPoint Verified.                                                                                                                                                                                                             | (b) (4), (b) (6)         | 17 Nov 2020 21:54:25 |
| User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal haemorrhages NEC, HLT: Non-site specific gastrointestinal haemorrhages, PT: Gastrointestinal haemorrhage, LLT: GI bleed - version MedDRA\23.0. | Coder Import (b) (4)     | 13 Nov 2020 23:26:35 |
| User coded data point as Term Coded data point by User: (b) (6) version MedDRA\23.0.                                                                                                                                            | Coder Import (b) (4)     | 13 Nov 2020 23:26:35 |
| Data point term sent to Coder                                                                                                                                                                                                   | System                   | 13 Nov 2020 19:49:41 |

US3762161

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:14:36

[Adverse event](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| User entered 'Possible GI Bleed' | (b) (4), (b) (6) | 13 Nov 2020 19:48:40 |
|                                  |                  |                      |

**US3762161**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 26 Nov 2020 11:14:36**

[Was this a medically-attended AE?](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 17 Nov 2020 21:54:25 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 13 Nov 2020 19:48:40 |

US3762161

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:14:36

[Was this a Solicited Adverse Reaction?](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 17 Nov 2020 21:54:25 |
| User entered 'No (N)' | (b) (4), (b) (6) | 13 Nov 2020 19:48:40 |

US3762161

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:14:36

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 17 Nov 2020 21:54:25 |
| User entered 'No (N)' | (b) (4), (b) (6) | 13 Nov 2020 19:48:40 |

US3762161

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:14:36

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

| Audit                     | User             | Time (GMT)           |
|---------------------------|------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6) | 17 Nov 2020 21:54:25 |
| User entered '9 Nov 2020' | (b) (4), (b) (6) | 13 Nov 2020 19:48:40 |



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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:14:36

[Start time \(00:00-23:59\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 17 Nov 2020 21:54:25 |
| User entered empty. | (b) (4), (b) (6) | 13 Nov 2020 19:48:40 |

US3762161

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:14:36

[AE start date and time \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 13 Nov 2020 19:48:40 |

US3762161

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:14:36

[Ongoing?](#)

| Audit                                                     | User                     | Time (GMT)           |
|-----------------------------------------------------------|--------------------------|----------------------|
| DataPoint Verified.                                       | (b) (4), (b) (6)         | 19 Nov 2020 18:05:46 |
| DataPoint Un-verified.                                    | Samantha Wheeler (b) (4) | 18 Nov 2020 20:07:18 |
| User entered 'No (N)' reason for change: Data Entry Error | (b) (4)                  | 18 Nov 2020 20:07:18 |
| DataPoint Verified.                                       | (b) (4), (b) (6)         | 17 Nov 2020 21:54:25 |
| User entered 'Yes (Y)'                                    | (b) (4), (b) (6)         | 13 Nov 2020 19:48:40 |

US3762161

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:14:36

If not Ongoing, end date (dd MMM yyyy)

| Audit                                                                                                                                                                       | User                     | Time (GMT)           |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|----------------------|
| DataPoint Verified.                                                                                                                                                         | (b) (4), (b) (6)         | 19 Nov 2020 18:05:46 |
| User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).             | System                   | 18 Nov 2020 20:09:21 |
| Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System). | System                   | 18 Nov 2020 20:09:21 |
| User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).             | System                   | 18 Nov 2020 20:07:18 |
| DataPoint Un-verified.                                                                                                                                                      | Samantha Wheeler (b) (4) | 18 Nov 2020 20:07:18 |
| User entered '15 Nov 2020' reason for change: Data Entry Error                                                                                                              | (b) (4)                  | 18 Nov 2020 20:07:18 |
| DataPoint Verified.                                                                                                                                                         | (b) (4), (b) (6)         | 17 Nov 2020 21:54:25 |
| User entered empty.                                                                                                                                                         | (b) (4), (b) (6)         | 13 Nov 2020 19:48:40 |

US3762161

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:14:36

[End time \(00:00-23:59\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 17 Nov 2020 21:54:25 |
| User entered empty. | (b) (4), (b) (6) | 13 Nov 2020 19:48:40 |

**US3762161**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 26 Nov 2020 11:14:36**

[AE End Date and Time \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 13 Nov 2020 19:48:40 |

US3762161

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:14:36

[Severity](#)

| Audit                                          | User             | Time (GMT)           |
|------------------------------------------------|------------------|----------------------|
| DataPoint Verified.                            | (b) (4), (b) (6) | 17 Nov 2020 21:54:25 |
| User entered 'Grade 3/Severe (Grade 3/Severe)' | (b) (4), (b) (6) | 13 Nov 2020 19:48:40 |

US3762161

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:14:36

[Is the adverse event serious?](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 17 Nov 2020 21:54:25 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 13 Nov 2020 19:48:40 |



US3762161

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:14:36

[Death](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 17 Nov 2020 21:54:25 |
| User entered '0'    | (b) (4), (b) (6) | 13 Nov 2020 19:48:40 |

US3762161

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:14:36

[Life threatening](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 17 Nov 2020 21:54:25 |
| User entered '1'    | (b) (4), (b) (6) | 13 Nov 2020 19:48:40 |

US3762161

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:14:36

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit                                                                                                                                                                                                                                                                          | User             | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).<br>DataPoint Verified.               | (b) (4), (b) (6) | 19 Nov 2020 17:26:39 |
|                                                                                                                                                                                                                                                                                | (b) (4), (b) (6) | 17 Nov 2020 21:54:25 |
| Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'Hospital admission date updated ' (Site from System). | (b) (4), (b) (6) | 13 Nov 2020 19:51:49 |
| User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).                                      | System           | 13 Nov 2020 19:48:40 |
| User entered '1'                                                                                                                                                                                                                                                               | (b) (4), (b) (6) | 13 Nov 2020 19:48:40 |

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:14:36

[Hospital Admission Date \(dd MMM yyyy\)](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 17 Nov 2020 21:54:25 |
| User entered '10 Nov 2020' | (b) (4), (b) (6) | 13 Nov 2020 19:48:40 |

US3762161

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:14:36

[Hospital Discharge Date \(dd MMM yyyy\)](#)

| Audit                                                          | User             | Time (GMT)           |
|----------------------------------------------------------------|------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6) | 24 Nov 2020 18:48:04 |
| DataPoint Un-verified.                                         | (b) (4), (b) (6) | 24 Nov 2020 18:30:33 |
| User entered '15 Nov 2020' reason for change: Data Entry Error | (b) (4), (b) (6) | 24 Nov 2020 18:30:33 |
| DataPoint Verified.                                            | (b) (4), (b) (6) | 17 Nov 2020 21:54:25 |
| User entered empty.                                            | (b) (4), (b) (6) | 13 Nov 2020 19:48:40 |

US3762161

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:14:36

[Admitted to ICU?](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 17 Nov 2020 21:54:25 |
| User entered 'No (N)' | (b) (4), (b) (6) | 13 Nov 2020 19:48:40 |

US3762161

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:14:36

[Number of Days in ICU](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 17 Nov 2020 21:54:25 |
| User entered empty. | (b) (4), (b) (6) | 13 Nov 2020 19:48:40 |

US3762161

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:14:36

[Persistent or significant disability or incapacity](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 17 Nov 2020 21:54:25 |
| User entered '0'    | (b) (4), (b) (6) | 13 Nov 2020 19:48:40 |



US3762161

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:14:36

[Congenital anomaly or birth defect](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 17 Nov 2020 21:54:25 |
| User entered '0'    | (b) (4), (b) (6) | 13 Nov 2020 19:48:40 |

US3762161

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:14:36

[Other medically important event](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 17 Nov 2020 21:54:25 |
| User entered '0'    | (b) (4), (b) (6) | 13 Nov 2020 19:48:40 |

US3762161

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:14:36

[Relationship to investigational product](#)

| Audit                                    | User             | Time (GMT)           |
|------------------------------------------|------------------|----------------------|
| DataPoint Verified.                      | (b) (4), (b) (6) | 17 Nov 2020 21:54:25 |
| User entered 'Not Related (NOT RELATED)' | (b) (4), (b) (6) | 13 Nov 2020 19:48:40 |

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:14:36

[Relationship to Study Procedure](#)

| Audit                                    | User             | Time (GMT)           |
|------------------------------------------|------------------|----------------------|
| DataPoint Verified.                      | (b) (4), (b) (6) | 17 Nov 2020 21:54:25 |
| User entered 'Not Related (NOT RELATED)' | (b) (4), (b) (6) | 13 Nov 2020 19:48:40 |

**US3762161**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 26 Nov 2020 11:14:36**

[Action taken with investigational product](#)

| Audit                                                                                 | User             | Time (GMT)           |
|---------------------------------------------------------------------------------------|------------------|----------------------|
| DataPoint Verified.                                                                   | (b) (4), (b) (6) | 24 Nov 2020 18:48:04 |
| DataPoint Un-verified.                                                                | (b) (4), (b) (6) | 24 Nov 2020 18:30:33 |
| User entered 'Not Applicable (NOT APPLICABLE)'<br>reason for change: Data Entry Error | (b) (4), (b) (6) | 24 Nov 2020 18:30:33 |
| DataPoint Verified.                                                                   | (b) (4), (b) (6) | 17 Nov 2020 21:54:25 |
| User entered 'None (NONE)'                                                            | (b) (4), (b) (6) | 13 Nov 2020 19:48:40 |

**US3762161**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 26 Nov 2020 11:14:36**

[None](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 17 Nov 2020 21:54:25 |
| User entered '0'    | (b) (4), (b) (6) | 13 Nov 2020 19:48:40 |

US3762161

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:14:36

[Concomitant Medication](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 17 Nov 2020 21:54:25 |
| User entered '1'    | (b) (4), (b) (6) | 13 Nov 2020 19:48:40 |

US3762161

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:14:36

[Concomitant Procedure](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 17 Nov 2020 21:54:25 |
| User entered '0'    | (b) (4), (b) (6) | 13 Nov 2020 19:48:40 |



US3762161

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:14:36

[Outcome](#)

| Audit                                                                     | User                     | Time (GMT)           |
|---------------------------------------------------------------------------|--------------------------|----------------------|
| DataPoint Verified.                                                       | (b) (4), (b) (6)         | 19 Nov 2020 18:05:46 |
| DataPoint Un-verified.                                                    | Samantha Wheeler (b) (4) | 18 Nov 2020 20:09:21 |
| User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: | (b) (4)                  |                      |
| Data Entry Error                                                          | Samantha Wheeler (b) (4) | 18 Nov 2020 20:09:21 |
| DataPoint Verified.                                                       | (b) (4), (b) (6)         | 17 Nov 2020 21:54:25 |
| User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'    | (b) (4), (b) (6)         | 13 Nov 2020 19:48:40 |

US3762161

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:14:36

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 17 Nov 2020 21:54:25 |
| User entered empty. | (b) (4), (b) (6) | 13 Nov 2020 19:48:40 |

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:14:36

[Narrative](#)

| Audit                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | User             | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| DataPoint Verified.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | (b) (4), (b) (6) | 17 Nov 2020 21:54:25 |
| User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | System           | 13 Nov 2020 19:51:32 |
| Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | System           | 13 Nov 2020 19:51:32 |
| User entered '74 Y/O MALE WHO RECEIVED SECOND DOSE OF PRODUCT ON 9/30 WITHOUT INCIDENT AND WAS SEEN FOR ROUTINE F/U ON 11/03 AND REPORTED NO SYMPTOMS WHO WAS ADMITTED TO WFBMC ON 11/10 WITH DIAGNOSIS OF GASTROENTERITIS WITH ASSOCIATED SEPSIS, ACUTE KIDNEY INJURY, AND POSSIBLE GI BLEED. HE HAD REPORTED FEELING TIRED WITH HEADACHES AND MUSCLE ACHES ON 11/09 AND WAS SEEN FOR A SICK VISIT. A PCR FOR COVID-19 WAS PERFORMED AT THE TIME WAS NEGATIVE. ON TELEPHONE F/U ON 11/10, HE REPORTED INCREASED FATIGUE AND DEVELOPMENT OF DIARRHEA WITH BLACK STOOL. WE RECOMMENDED GOING TO EDC (WHICH HAD ALSO BEEN RECOMMENDED BY PCP). HE WAS ADMITTED FROM THE ED AND DIAGNOSED AS ABOVE.' reason for change: Data Entry Error | (b) (4), (b) (6) | 13 Nov 2020 19:51:32 |
| User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | System           | 13 Nov 2020 19:48:40 |
| User entered empty.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | (b) (4), (b) (6) | 13 Nov 2020 19:48:40 |

US3762161

**Folder:** Adverse Events

**Form:** Adverse Events (3)

**Generated On:** 26 Nov 2020 11:14:36

Serious Adverse Event Derived (CSA Programming Field Only)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 13 Nov 2020 19:48:40 |

**US3762161**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 26 Nov 2020 11:14:36**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 13 Nov 2020 19:48:40 |

**US3762161**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 26 Nov 2020 11:14:36**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '0' | System | 13 Nov 2020 19:48:40 |

**US3762161**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 26 Nov 2020 11:14:36**

[AEID](#)

| Audit                                                 | User             | Time (GMT)           |
|-------------------------------------------------------|------------------|----------------------|
| DataPoint Verified.                                   | (b) (4), (b) (6) | 19 Nov 2020 18:05:46 |
| Reviewed for Safety.                                  | (b) (4), (b) (6) | 18 Nov 2020 14:55:09 |
| User entered<br>'USA-US130-2020-mRNA-1273-P301000001' | (b) (4), (b) (6) | 18 Nov 2020 14:55:00 |

US3762161

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:14:36

[Adverse event](#)

| Audit                                                                                                                                                                                                             | User                     | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|----------------------|
| DataPoint Verified.                                                                                                                                                                                               | (b) (4), (b) (6)         | 19 Nov 2020 18:05:46 |
| User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Lower respiratory tract and lung infections, PT: Pneumonia, LLT: Lobar pneumonia - version MedDRA\\23.0. | Coder Import (b) (4)     | 18 Nov 2020 14:32:08 |
| User coded data point as Term Coded data point by User: (b) (6) version MedDRA\\23.0.                                                                                                                             | Coder Import (b) (4)     | 18 Nov 2020 14:32:08 |
| Data point term sent to Coder                                                                                                                                                                                     | System                   | 18 Nov 2020 14:04:45 |
| User entered 'Left Upper lobe pneumonia'                                                                                                                                                                          | Samantha Wheeler (b) (4) | 18 Nov 2020 14:04:06 |
|                                                                                                                                                                                                                   | (b) (4)                  |                      |



US3762161

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:14:36

[Was this a medically-attended AE?](#)

| Audit                  | User                     | Time (GMT)           |
|------------------------|--------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)         | 19 Nov 2020 18:05:46 |
| User entered 'Yes (Y)' | Samantha Wheeler (b) (4) | 18 Nov 2020 14:04:06 |
|                        | (b) (4)                  |                      |

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:14:36

[Was this a Solicited Adverse Reaction?](#)

| Audit                 | User                     | Time (GMT)           |
|-----------------------|--------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)         | 19 Nov 2020 18:05:46 |
| User entered 'No (N)' | Samantha Wheeler (b) (4) | 18 Nov 2020 14:04:06 |
|                       | (b) (4)                  |                      |

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:14:36

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit                 | User                     | Time (GMT)           |
|-----------------------|--------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)         | 19 Nov 2020 18:05:46 |
| User entered 'No (N)' | Samantha Wheeler (b) (4) | 18 Nov 2020 14:04:06 |
|                       | (b) (4)                  |                      |

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:14:36

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

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)         | 19 Nov 2020 18:05:46 |
| User entered '10 Nov 2020' | Samantha Wheeler (b) (4) | 18 Nov 2020 14:04:06 |
|                            | (b) (4)                  |                      |

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:14:36

Start time (00:00-23:59)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 19 Nov 2020 18:05:46 |
| User entered empty. | Samantha Wheeler (b) (4) | 18 Nov 2020 14:04:06 |
|                     | (b) (4)                  |                      |

US3762161

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:14:36

[AE start date and time \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 18 Nov 2020 14:04:06 |

US3762161

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:14:36

[Ongoing?](#)

| Audit                                                     | User                     | Time (GMT)           |
|-----------------------------------------------------------|--------------------------|----------------------|
| DataPoint Verified.                                       | (b) (4), (b) (6)         | 24 Nov 2020 20:10:53 |
| DataPoint Un-verified.                                    | Samantha Wheeler (b) (4) | 24 Nov 2020 19:19:14 |
| User entered 'No (N)' reason for change: Data Entry Error | (b) (4)                  | 24 Nov 2020 19:19:14 |
| DataPoint Verified.                                       | (b) (4), (b) (6)         | 19 Nov 2020 18:05:46 |
| User entered 'Yes (Y)'                                    | Samantha Wheeler (b) (4) | 18 Nov 2020 14:04:06 |

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:14:36

If not Ongoing, end date (dd MMM yyyy)

| Audit                                                          | User                     | Time (GMT)           |
|----------------------------------------------------------------|--------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)         | 24 Nov 2020 20:10:53 |
| DataPoint Un-verified.                                         | Samantha Wheeler (b) (4) | 24 Nov 2020 19:19:14 |
| User entered '18 Nov 2020' reason for change: Data Entry Error | (b) (4)                  | 24 Nov 2020 19:19:14 |
| DataPoint Verified.                                            | (b) (4), (b) (6)         | 19 Nov 2020 18:05:46 |
| User entered empty.                                            | Samantha Wheeler (b) (4) | 18 Nov 2020 14:04:06 |
|                                                                | (b) (4)                  |                      |



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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:14:36

End time (00:00-23:59)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 19 Nov 2020 18:05:46 |
| User entered empty. | Samantha Wheeler (b) (4) | 18 Nov 2020 14:04:06 |
|                     | (b) (4)                  |                      |

US3762161

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:14:36

[AE End Date and Time \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 18 Nov 2020 14:04:06 |

US3762161

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:14:36

[Severity](#)

| Audit                                          | User                     | Time (GMT)           |
|------------------------------------------------|--------------------------|----------------------|
| DataPoint Verified.                            | (b) (4), (b) (6)         | 19 Nov 2020 18:05:46 |
| User entered 'Grade 3/Severe (Grade 3/Severe)' | Samantha Wheeler (b) (4) | 18 Nov 2020 14:04:06 |
|                                                | (b) (4)                  |                      |

US3762161

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:14:36

[Is the adverse event serious?](#)

| Audit                                                                                                                                                                        | User                                | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|----------------------|
| DataPoint Verified.                                                                                                                                                          | (b) (4), (b) (6)                    | 19 Nov 2020 18:05:46 |
| User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System). | System                              | 18 Nov 2020 14:04:31 |
| User opened query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System). | System                              | 18 Nov 2020 14:04:06 |
| User entered 'Yes (Y)'                                                                                                                                                       | Samantha Wheeler (b) (4)<br>(b) (4) | 18 Nov 2020 14:04:06 |

US3762161

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:14:36

[Death](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 19 Nov 2020 18:05:46 |
| User entered '0'    | Samantha Wheeler (b) (4) | 18 Nov 2020 14:04:06 |
|                     | (b) (4)                  |                      |

US3762161

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:14:36

[Life threatening](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 19 Nov 2020 18:05:46 |
| User entered '0'    | Samantha Wheeler (b) (4) | 18 Nov 2020 14:04:06 |
|                     | (b) (4)                  |                      |

US3762161

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:14:36

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit                                                                                                                                                                                          | User                     | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|----------------------|
| DataPoint Verified.                                                                                                                                                                            | (b) (4), (b) (6)         | 19 Nov 2020 18:05:46 |
| User closed query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).             |                          | 18 Nov 2020 14:04:31 |
| Query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered by data change (Site from System). |                          | 18 Nov 2020 14:04:31 |
| User entered '1' reason for change: Data Entry Error                                                                                                                                           | Samantha Wheeler (b) (4) | 18 Nov 2020 14:04:31 |
| User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).             | (b) (4)                  | 18 Nov 2020 14:04:06 |
| User entered '0'                                                                                                                                                                               | Samantha Wheeler (b) (4) | 18 Nov 2020 14:04:06 |

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:14:36

Hospital Admission Date (*dd MMM yyyy*)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)         | 19 Nov 2020 18:05:46 |
| User entered '10 Nov 2020' | Samantha Wheeler (b) (4) | 18 Nov 2020 14:04:06 |
|                            | (b) (4)                  |                      |



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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:14:36

Hospital Discharge Date (dd MMM yyyy)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)         | 19 Nov 2020 18:05:46 |
| User entered '15 Nov 2020' | Samantha Wheeler (b) (4) | 18 Nov 2020 14:04:06 |
|                            | (b) (4)                  |                      |

US3762161

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:14:36

[Admitted to ICU?](#)

| Audit                 | User                     | Time (GMT)           |
|-----------------------|--------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)         | 19 Nov 2020 18:05:46 |
| User entered 'No (N)' | Samantha Wheeler (b) (4) | 18 Nov 2020 14:04:06 |
|                       | (b) (4)                  |                      |

US3762161

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:14:36

[Number of Days in ICU](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 19 Nov 2020 18:05:46 |
| User entered empty. | Samantha Wheeler (b) (4) | 18 Nov 2020 14:04:06 |
|                     | (b) (4)                  |                      |

US3762161

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:14:36

[Persistent or significant disability or incapacity](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 19 Nov 2020 18:05:46 |
| User entered '0'    | Samantha Wheeler (b) (4) | 18 Nov 2020 14:04:06 |
|                     | (b) (4)                  |                      |

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:14:36

[Congenital anomaly or birth defect](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 19 Nov 2020 18:05:46 |
| User entered '0'    | Samantha Wheeler (b) (4) | 18 Nov 2020 14:04:06 |
|                     | (b) (4)                  |                      |

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:14:36

[Other medically important event](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 19 Nov 2020 18:05:46 |
| User entered '0'    | Samantha Wheeler (b) (4) | 18 Nov 2020 14:04:06 |
|                     | (b) (4)                  |                      |

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:14:36

[Relationship to investigational product](#)

| Audit                                    | User                     | Time (GMT)           |
|------------------------------------------|--------------------------|----------------------|
| DataPoint Verified.                      | (b) (4), (b) (6)         | 19 Nov 2020 18:05:46 |
| User entered 'Not Related (NOT RELATED)' | Samantha Wheeler (b) (4) | 18 Nov 2020 14:04:06 |
|                                          | (b) (4)                  |                      |

US3762161

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:14:36

[Relationship to Study Procedure](#)

| Audit                                    | User                     | Time (GMT)           |
|------------------------------------------|--------------------------|----------------------|
| DataPoint Verified.                      | (b) (4), (b) (6)         | 19 Nov 2020 18:05:46 |
| User entered 'Not Related (NOT RELATED)' | Samantha Wheeler (b) (4) | 18 Nov 2020 14:04:06 |
|                                          | (b) (4)                  |                      |



US3762161

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:14:36

[Action taken with investigational product](#)

| Audit                                          | User                     | Time (GMT)           |
|------------------------------------------------|--------------------------|----------------------|
| DataPoint Verified.                            | (b) (4), (b) (6)         | 24 Nov 2020 18:48:04 |
| DataPoint Un-verified.                         | (b) (4), (b) (6)         | 24 Nov 2020 18:31:02 |
| User entered 'Not Applicable (NOT APPLICABLE)' | (b) (4), (b) (6)         | 24 Nov 2020 18:31:02 |
| reason for change: Data Entry Error            |                          |                      |
| DataPoint Verified.                            | (b) (4), (b) (6)         | 19 Nov 2020 18:05:46 |
| User entered 'None (NONE)'                     | Samantha Wheeler (b) (4) | 18 Nov 2020 14:04:06 |
|                                                | (b) (4)                  |                      |

US3762161

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:14:36

[None](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 19 Nov 2020 18:05:46 |
| User entered '0'    | Samantha Wheeler (b) (4) | 18 Nov 2020 14:04:06 |
|                     | (b) (4)                  |                      |

US3762161

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:14:36

[Concomitant Medication](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 19 Nov 2020 18:05:46 |
| User entered '1'    | Samantha Wheeler (b) (4) | 18 Nov 2020 14:04:06 |
|                     | (b) (4)                  |                      |

US3762161

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:14:36

[Concomitant Procedure](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 19 Nov 2020 18:05:46 |
| User entered '0'    | Samantha Wheeler (b) (4) | 18 Nov 2020 14:04:06 |
|                     | (b) (4)                  |                      |

US3762161

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:14:36

[Outcome](#)

| Audit                                                                     | User                     | Time (GMT)           |
|---------------------------------------------------------------------------|--------------------------|----------------------|
| DataPoint Verified.                                                       | (b) (4), (b) (6)         | 24 Nov 2020 20:10:53 |
| DataPoint Un-verified.                                                    | Samantha Wheeler (b) (4) | 24 Nov 2020 19:19:14 |
| User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: | (b) (4)                  |                      |
| Data Entry Error                                                          | Samantha Wheeler (b) (4) | 24 Nov 2020 19:19:14 |
| DataPoint Verified.                                                       | (b) (4), (b) (6)         | 19 Nov 2020 18:05:46 |
| User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'    | Samantha Wheeler (b) (4) | 18 Nov 2020 14:04:06 |
|                                                                           | (b) (4)                  |                      |

US3762161

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:14:36

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 19 Nov 2020 18:05:46 |
| User entered empty. | Samantha Wheeler (b) (4) | 18 Nov 2020 14:04:06 |
|                     | (b) (4)                  |                      |

US3762161

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:14:36

[Narrative](#)

| Audit                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | User                     | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|----------------------|
| DataPoint Verified.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | (b) (4), (b) (6)         | 24 Nov 2020 20:26:41 |
| DataPoint Un-verified.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | Samantha Wheeler (b) (4) | 24 Nov 2020 20:13:19 |
| User entered '74 Y/O MALE WHO RECEIVED SECOND DOSE OF PRODUCT ON 9/30 WITHOUT INCIDENT AND WAS SEEN FOR ROUTINE F/U ON 11/03 AND REPORTED NO SYMPTOMS WHO WAS ADMITTED TO WFBMC ON 11/10 WITH DIAGNOSIS OF GASTROENTERITIS WITH ASSOCIATED SEPSIS, ACUTE KIDNEY INJURY, AND POSSIBLE GI BLEED. HE HAD REPORTED FEELING TIRED WITH HEADACHES AND MUSCLE ACHES ON 11/09 AND WAS SEEN FOR A SICK VISIT. A PCR FOR COVID-19 WAS PERFORMED AT THE TIME WAS NEGATIVE. ON TELEPHONE F/U ON 11/10, HE REPORTED INCREASED FATIGUE AND DEVELOPMENT OF DIARRHEA WITH BLACK STOOL. WE RECOMMENDED GOING TO EDC (WHICH HAD ALSO BEEN RECOMMENDED BY PCP). HE WAS ADMITTED FROM THE ED AND DIAGNOSED AS ABOVE. | Samantha Wheeler (b) (4) | 24 Nov 2020 20:13:19 |
| ct chest scan without contrast was performed' reason for change: Data Entry Error                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                          |                      |
| DataPoint Verified.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | (b) (4), (b) (6)         | 19 Nov 2020 18:05:46 |
| User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | System                   | 18 Nov 2020 14:05:10 |
| Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | System                   | 18 Nov 2020 14:05:10 |

US3762161

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:14:36

[Narrative](#)

| Audit                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | User                     | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|----------------------|
| User entered '74 Y/O MALE WHO RECEIVED SECOND DOSE OF PRODUCT ON 9/30 WITHOUT INCIDENT AND WAS SEEN FOR ROUTINE F/U ON 11/03 AND REPORTED NO SYMPTOMS WHO WAS ADMITTED TO WFBMC ON 11/10 WITH DIAGNOSIS OF GASTROENTERITIS WITH ASSOCIATED SEPSIS, ACUTE KIDNEY INJURY, AND POSSIBLE GI BLEED. HE HAD REPORTED FEELING TIRED WITH HEADACHES AND MUSCLE ACHES ON 11/09 AND WAS SEEN FOR A SICK VISIT. A PCR FOR COVID-19 WAS PERFORMED AT THE TIME WAS NEGATIVE. ON TELEPHONE F/U ON 11/10, HE REPORTED INCREASED FATIGUE AND DEVELOPMENT OF DIARRHEA WITH BLACK STOOL. WE RECOMMENDED GOING TO EDC (WHICH HAD ALSO BEEN RECOMMENDED BY PCP). HE WAS ADMITTED FROM THE ED AND DIAGNOSED AS ABOVE.' reason for change: Data Entry Error | Samantha Wheeler (b) (4) | 18 Nov 2020 14:05:10 |
| User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | System                   | 18 Nov 2020 14:04:06 |
| User entered empty.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | Samantha Wheeler (b) (4) | 18 Nov 2020 14:04:06 |



**US3762161**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 26 Nov 2020 11:14:36**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 18 Nov 2020 14:04:06 |

US3762161

**Folder:** Adverse Events

**Form:** Adverse Events (4)

**Generated On:** 26 Nov 2020 11:14:36

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 18 Nov 2020 14:04:06 |

**US3762161**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 26 Nov 2020 11:14:36**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '0' | System | 18 Nov 2020 14:04:06 |

**US3762161**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 26 Nov 2020 11:14:36**

[AEID](#)

| Audit                                                 | User             | Time (GMT)           |
|-------------------------------------------------------|------------------|----------------------|
| DataPoint Verified.                                   | (b) (4), (b) (6) | 19 Nov 2020 18:05:46 |
| Reviewed for Safety.                                  | (b) (4), (b) (6) | 18 Nov 2020 14:56:23 |
| User entered<br>'USA-US130-2020-mRNA-1273-P301000001' | (b) (4), (b) (6) | 18 Nov 2020 14:56:14 |

US3762161

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:14:36

[Adverse event](#)

| Audit                                                                                                                                                                                                 | User                                | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|----------------------|
| DataPoint Verified.                                                                                                                                                                                   | (b) (4), (b) (6)                    | 19 Nov 2020 18:05:46 |
| User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Electrolyte and fluid balance conditions, HLT: Sodium imbalance, PT: Hyponatraemia, LLT: Hyponatremia - version MedDRA\\23.0. | Coder Import (b) (4)<br>(b) (4)     | 18 Nov 2020 14:26:06 |
| User coded data point as Term Coded data point by User: (b) (6) version MedDRA\\23.0.                                                                                                                 | Coder Import (b) (4)<br>(b) (4)     | 18 Nov 2020 14:26:06 |
| Data point term sent to Coder                                                                                                                                                                         | System                              | 18 Nov 2020 14:24:58 |
| User entered 'Acute hyponatremia'                                                                                                                                                                     | Samantha Wheeler (b) (4)<br>(b) (4) | 18 Nov 2020 14:24:29 |

US3762161

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:14:36

[Was this a medically-attended AE?](#)

| Audit                  | User                     | Time (GMT)           |
|------------------------|--------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)         | 19 Nov 2020 18:05:46 |
| User entered 'Yes (Y)' | Samantha Wheeler (b) (4) | 18 Nov 2020 14:24:29 |
|                        | (b) (4)                  |                      |

US3762161

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:14:36

[Was this a Solicited Adverse Reaction?](#)

| Audit                 | User                     | Time (GMT)           |
|-----------------------|--------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)         | 19 Nov 2020 18:05:46 |
| User entered 'No (N)' | Samantha Wheeler (b) (4) | 18 Nov 2020 14:24:29 |
|                       | (b) (4)                  |                      |

US3762161

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:14:36

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit                 | User                     | Time (GMT)           |
|-----------------------|--------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)         | 19 Nov 2020 18:05:46 |
| User entered 'No (N)' | Samantha Wheeler (b) (4) | 18 Nov 2020 14:24:29 |
|                       | (b) (4)                  |                      |



US3762161

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:14:36

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

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)         | 19 Nov 2020 18:05:46 |
| User entered '10 Nov 2020' | Samantha Wheeler (b) (4) | 18 Nov 2020 14:24:29 |
|                            | (b) (4)                  |                      |

US3762161

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:14:36

Start time (00:00-23:59)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 19 Nov 2020 18:05:46 |
| User entered empty. | Samantha Wheeler (b) (4) | 18 Nov 2020 14:24:29 |
|                     | (b) (4)                  |                      |

**US3762161**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 26 Nov 2020 11:14:36**

[AE start date and time \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 18 Nov 2020 14:24:29 |

US3762161

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:14:36

[Ongoing?](#)

| Audit                                                                                  | User                     | Time (GMT)           |
|----------------------------------------------------------------------------------------|--------------------------|----------------------|
| DataPoint Verified.                                                                    | (b) (4), (b) (6)         | 19 Nov 2020 18:05:46 |
| User closed query 'Data is required. Please complete.' (Site from System).             | System                   | 18 Nov 2020 14:24:56 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System                   | 18 Nov 2020 14:24:56 |
| User entered 'No (N)' reason for change: Data Entry Error                              | Samantha Wheeler (b) (4) | 18 Nov 2020 14:24:56 |
| User opened query 'Data is required. Please complete.' (Site from System).             | System                   | 18 Nov 2020 14:24:29 |
| User entered empty.                                                                    | Samantha Wheeler (b) (4) | 18 Nov 2020 14:24:29 |

US3762161

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:14:36

If not Ongoing, end date (dd MMM yyyy)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)         | 19 Nov 2020 18:05:46 |
| User entered '15 Nov 2020' | Samantha Wheeler (b) (4) | 18 Nov 2020 14:24:29 |
|                            | (b) (4)                  |                      |

US3762161

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:14:36

End time (00:00-23:59)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 19 Nov 2020 18:05:46 |
| User entered empty. | Samantha Wheeler (b) (4) | 18 Nov 2020 14:24:29 |
|                     | (b) (4)                  |                      |

US3762161

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:14:36

[AE End Date and Time \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 18 Nov 2020 14:24:29 |

US3762161

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:14:36

[Severity](#)

| Audit                                      | User                     | Time (GMT)           |
|--------------------------------------------|--------------------------|----------------------|
| DataPoint Verified.                        | (b) (4), (b) (6)         | 19 Nov 2020 18:05:46 |
| User entered 'Grade 1/Mild (Grade 1/Mild)' | Samantha Wheeler (b) (4) | 18 Nov 2020 14:24:29 |
|                                            | (b) (4)                  |                      |



US3762161

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:14:36

[Is the adverse event serious?](#)

| Audit                  | User                     | Time (GMT)           |
|------------------------|--------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)         | 19 Nov 2020 18:05:46 |
| User entered 'Yes (Y)' | Samantha Wheeler (b) (4) | 18 Nov 2020 14:24:29 |
|                        | (b) (4)                  |                      |

US3762161

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:14:36

[Death](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 19 Nov 2020 18:05:46 |
| User entered '0'    | Samantha Wheeler (b) (4) | 18 Nov 2020 14:24:29 |
|                     | (b) (4)                  |                      |

US3762161

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:14:36

[Life threatening](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 19 Nov 2020 18:05:46 |
| User entered '0'    | Samantha Wheeler (b) (4) | 18 Nov 2020 14:24:29 |
|                     | (b) (4)                  |                      |

US3762161

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:14:36

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 19 Nov 2020 18:05:46 |
| User entered '1'    | Samantha Wheeler (b) (4) | 18 Nov 2020 14:24:29 |
|                     | (b) (4)                  |                      |

US3762161

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:14:36

Hospital Admission Date (*dd MMM yyyy*)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)         | 19 Nov 2020 18:05:46 |
| User entered '10 Nov 2020' | Samantha Wheeler (b) (4) | 18 Nov 2020 14:24:29 |
|                            | (b) (4)                  |                      |

US3762161

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:14:36

Hospital Discharge Date (dd MMM yyyy)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)         | 19 Nov 2020 18:05:46 |
| User entered '15 Nov 2020' | Samantha Wheeler (b) (4) | 18 Nov 2020 14:24:29 |
|                            | (b) (4)                  |                      |

US3762161

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:14:36

[Admitted to ICU?](#)

| Audit                 | User                     | Time (GMT)           |
|-----------------------|--------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)         | 19 Nov 2020 18:05:46 |
| User entered 'No (N)' | Samantha Wheeler (b) (4) | 18 Nov 2020 14:24:29 |
|                       | (b) (4)                  |                      |

US3762161

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:14:36

[Number of Days in ICU](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 19 Nov 2020 18:05:46 |
| User entered empty. | Samantha Wheeler (b) (4) | 18 Nov 2020 14:24:29 |
|                     | (b) (4)                  |                      |



US3762161

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:14:36

[Persistent or significant disability or incapacity](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 19 Nov 2020 18:05:46 |
| User entered '0'    | Samantha Wheeler (b) (4) | 18 Nov 2020 14:24:29 |
|                     | (b) (4)                  |                      |

US3762161

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:14:36

[Congenital anomaly or birth defect](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 19 Nov 2020 18:05:46 |
| User entered '0'    | Samantha Wheeler (b) (4) | 18 Nov 2020 14:24:29 |
|                     | (b) (4)                  |                      |

US3762161

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:14:36

[Other medically important event](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 19 Nov 2020 18:05:46 |
| User entered '0'    | Samantha Wheeler (b) (4) | 18 Nov 2020 14:24:29 |
|                     | (b) (4)                  |                      |

US3762161

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:14:36

[Relationship to investigational product](#)

| Audit                                    | User                     | Time (GMT)           |
|------------------------------------------|--------------------------|----------------------|
| DataPoint Verified.                      | (b) (4), (b) (6)         | 19 Nov 2020 18:05:46 |
| User entered 'Not Related (NOT RELATED)' | Samantha Wheeler (b) (4) | 18 Nov 2020 14:24:29 |
|                                          | (b) (4)                  |                      |

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:14:36

[Relationship to Study Procedure](#)

| Audit                                    | User                     | Time (GMT)           |
|------------------------------------------|--------------------------|----------------------|
| DataPoint Verified.                      | (b) (4), (b) (6)         | 19 Nov 2020 18:05:46 |
| User entered 'Not Related (NOT RELATED)' | Samantha Wheeler (b) (4) | 18 Nov 2020 14:24:29 |
|                                          | (b) (4)                  |                      |

US3762161

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:14:36

[Action taken with investigational product](#)

| Audit                                          | User                     | Time (GMT)           |
|------------------------------------------------|--------------------------|----------------------|
| DataPoint Verified.                            | (b) (4), (b) (6)         | 24 Nov 2020 19:12:41 |
| DataPoint Un-verified.                         | (b) (4), (b) (6)         | 24 Nov 2020 19:07:52 |
| User entered 'Not Applicable (NOT APPLICABLE)' | (b) (4), (b) (6)         | 24 Nov 2020 19:07:52 |
| reason for change: Data Entry Error            |                          |                      |
| DataPoint Verified.                            | (b) (4), (b) (6)         | 19 Nov 2020 18:05:46 |
| User entered 'None (NONE)'                     | Samantha Wheeler (b) (4) | 18 Nov 2020 14:24:29 |
|                                                | (b) (4)                  |                      |

US3762161

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:14:36

[None](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 19 Nov 2020 18:05:46 |
| User entered '1'    | Samantha Wheeler (b) (4) | 18 Nov 2020 14:24:29 |
|                     | (b) (4)                  |                      |

US3762161

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:14:36

[Concomitant Medication](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 19 Nov 2020 18:05:46 |
| User entered '0'    | Samantha Wheeler (b) (4) | 18 Nov 2020 14:24:29 |
|                     | (b) (4)                  |                      |



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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:14:36

[Concomitant Procedure](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 19 Nov 2020 18:05:46 |
| User entered '0'    | Samantha Wheeler (b) (4) | 18 Nov 2020 14:24:29 |
|                     | (b) (4)                  |                      |

US3762161

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:14:36

[Outcome](#)

| Audit                                                  | User                     | Time (GMT)           |
|--------------------------------------------------------|--------------------------|----------------------|
| DataPoint Verified.                                    | (b) (4), (b) (6)         | 19 Nov 2020 18:05:46 |
| User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' | Samantha Wheeler (b) (4) | 18 Nov 2020 14:24:29 |
|                                                        | (b) (4)                  |                      |

US3762161

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:14:36

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 19 Nov 2020 18:05:46 |
| User entered empty. | Samantha Wheeler (b) (4) | 18 Nov 2020 14:24:29 |
|                     | (b) (4)                  |                      |

US3762161

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:14:36

[Narrative](#)

| Audit                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | User                                | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|----------------------|
| DataPoint Verified.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | (b) (4), (b) (6)                    | 19 Nov 2020 18:05:46 |
| User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | System                              | 18 Nov 2020 14:25:49 |
| Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | System                              | 18 Nov 2020 14:25:49 |
| User entered '74 Y/O MALE WHO RECEIVED SECOND DOSE OF PRODUCT ON 9/30 WITHOUT INCIDENT AND WAS SEEN FOR ROUTINE F/U ON 11/03 AND REPORTED NO SYMPTOMS WHO WAS ADMITTED TO WFBMC ON 11/10 WITH DIAGNOSIS OF GASTROENTERITIS WITH ASSOCIATED SEPSIS, ACUTE KIDNEY INJURY, AND POSSIBLE GI BLEED. HE HAD REPORTED FEELING TIRED WITH HEADACHES AND MUSCLE ACHES ON 11/09 AND WAS SEEN FOR A SICK VISIT. A PCR FOR COVID-19 WAS PERFORMED AT THE TIME WAS NEGATIVE. ON TELEPHONE F/U ON 11/10, HE REPORTED INCREASED FATIGUE AND DEVELOPMENT OF DIARRHEA WITH BLACK STOOL. WE RECOMMENDED GOING TO EDC (WHICH HAD ALSO BEEN RECOMMENDED BY PCP). HE WAS ADMITTED FROM THE ED AND DIAGNOSED AS ABOVE.' reason for change: Data Entry Error | Samantha Wheeler (b) (4)<br>(b) (4) | 18 Nov 2020 14:25:49 |
| User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | System                              | 18 Nov 2020 14:24:29 |
| User entered empty.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | Samantha Wheeler (b) (4)<br>(b) (4) | 18 Nov 2020 14:24:29 |

**US3762161**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 26 Nov 2020 11:14:36**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 18 Nov 2020 14:24:29 |

**US3762161**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 26 Nov 2020 11:14:36**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 18 Nov 2020 14:24:29 |

**US3762161**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 26 Nov 2020 11:14:36**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '0' | System | 18 Nov 2020 14:24:29 |

**US3762161**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 26 Nov 2020 11:14:36**

[AEID](#)

| Audit                                                 | User             | Time (GMT)           |
|-------------------------------------------------------|------------------|----------------------|
| DataPoint Verified.                                   | (b) (4), (b) (6) | 19 Nov 2020 18:05:46 |
| Reviewed for Safety.                                  | (b) (4), (b) (6) | 18 Nov 2020 14:58:42 |
| User entered<br>'USA-US130-2020-mRNA-1273-P301000001' | (b) (4), (b) (6) | 18 Nov 2020 14:58:37 |



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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:14:36

[Adverse event](#)

| Audit                                                                                                                                                                                                  | User                                | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|----------------------|
| DataPoint Verified.                                                                                                                                                                                    | (b) (4), (b) (6)                    | 19 Nov 2020 18:05:46 |
| User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Electrolyte and fluid balance conditions, HLT: Potassium imbalance, PT: Hypokalaemia, LLT: Hypokalemia - version MedDRA\\23.0. | Coder Import (b) (4)<br>(b) (4)     | 18 Nov 2020 14:32:06 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.                                                                                                           | Coder Import (b) (4)<br>(b) (4)     | 18 Nov 2020 14:32:06 |
| Data point term sent to Coder                                                                                                                                                                          | System                              | 18 Nov 2020 14:31:02 |
| User entered 'hypokalemia'                                                                                                                                                                             | Samantha Wheeler (b) (4)<br>(b) (4) | 18 Nov 2020 14:30:13 |

US3762161

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:14:36

[Was this a medically-attended AE?](#)

| Audit                  | User                     | Time (GMT)           |
|------------------------|--------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)         | 19 Nov 2020 18:05:46 |
| User entered 'Yes (Y)' | Samantha Wheeler (b) (4) | 18 Nov 2020 14:30:13 |
|                        | (b) (4)                  |                      |

US3762161

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:14:36

[Was this a Solicited Adverse Reaction?](#)

| Audit                 | User                     | Time (GMT)           |
|-----------------------|--------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)         | 19 Nov 2020 18:05:46 |
| User entered 'No (N)' | Samantha Wheeler (b) (4) | 18 Nov 2020 14:30:13 |
|                       | (b) (4)                  |                      |

US3762161

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:14:36

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit                 | User                     | Time (GMT)           |
|-----------------------|--------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)         | 19 Nov 2020 18:05:46 |
| User entered 'No (N)' | Samantha Wheeler (b) (4) | 18 Nov 2020 14:30:13 |
|                       | (b) (4)                  |                      |

US3762161

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:14:36

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

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)         | 19 Nov 2020 18:05:46 |
| User entered '10 Nov 2020' | Samantha Wheeler (b) (4) | 18 Nov 2020 14:30:13 |
|                            | (b) (4)                  |                      |

US3762161

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:14:36

[Start time \(00:00-23:59\)](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 19 Nov 2020 18:05:46 |
| User entered empty. | Samantha Wheeler (b) (4) | 18 Nov 2020 14:30:13 |
|                     | (b) (4)                  |                      |

US3762161

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:14:36

[AE start date and time \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 18 Nov 2020 14:30:13 |

US3762161

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:14:36

[Ongoing?](#)

| Audit                 | User                     | Time (GMT)           |
|-----------------------|--------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)         | 19 Nov 2020 18:05:46 |
| User entered 'No (N)' | Samantha Wheeler (b) (4) | 18 Nov 2020 14:30:13 |
|                       | (b) (4)                  |                      |



US3762161

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:14:36

If not Ongoing, end date (dd MMM yyyy)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)         | 19 Nov 2020 18:05:46 |
| User entered '15 Nov 2020' | Samantha Wheeler (b) (4) | 18 Nov 2020 14:30:13 |
|                            | (b) (4)                  |                      |

US3762161

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:14:36

End time (00:00-23:59)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 19 Nov 2020 18:05:46 |
| User entered empty. | Samantha Wheeler (b) (4) | 18 Nov 2020 14:30:13 |
|                     | (b) (4)                  |                      |

**US3762161**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 26 Nov 2020 11:14:36**

[AE End Date and Time \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 18 Nov 2020 14:30:13 |

**US3762161**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 26 Nov 2020 11:14:36**

[Severity](#)

| Audit                                      | User                     | Time (GMT)           |
|--------------------------------------------|--------------------------|----------------------|
| DataPoint Verified.                        | (b) (4), (b) (6)         | 19 Nov 2020 18:05:46 |
| User entered 'Grade 1/Mild (Grade 1/Mild)' | Samantha Wheeler (b) (4) | 18 Nov 2020 14:30:13 |
|                                            | (b) (4)                  |                      |

US3762161

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:14:36

[Is the adverse event serious?](#)

| Audit                  | User                     | Time (GMT)           |
|------------------------|--------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)         | 19 Nov 2020 18:05:46 |
| User entered 'Yes (Y)' | Samantha Wheeler (b) (4) | 18 Nov 2020 14:30:13 |
|                        | (b) (4)                  |                      |

US3762161

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:14:36

[Death](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 19 Nov 2020 18:05:46 |
| User entered '0'    | Samantha Wheeler (b) (4) | 18 Nov 2020 14:30:13 |
|                     | (b) (4)                  |                      |

US3762161

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:14:36

[Life threatening](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 19 Nov 2020 18:05:46 |
| User entered '0'    | Samantha Wheeler (b) (4) | 18 Nov 2020 14:30:13 |
|                     | (b) (4)                  |                      |

US3762161

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:14:36

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 19 Nov 2020 18:05:46 |
| User entered '1'    | Samantha Wheeler (b) (4) | 18 Nov 2020 14:30:13 |
|                     | (b) (4)                  |                      |



US3762161

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:14:36

Hospital Admission Date (*dd MMM yyyy*)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)         | 19 Nov 2020 18:05:46 |
| User entered '10 Nov 2020' | Samantha Wheeler (b) (4) | 18 Nov 2020 14:30:13 |
|                            | (b) (4)                  |                      |

US3762161

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:14:36

Hospital Discharge Date (dd MMM yyyy)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)         | 19 Nov 2020 18:05:46 |
| User entered '15 Nov 2020' | Samantha Wheeler (b) (4) | 18 Nov 2020 14:30:13 |
|                            | (b) (4)                  |                      |

US3762161

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:14:36

[Admitted to ICU?](#)

| Audit                 | User                     | Time (GMT)           |
|-----------------------|--------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)         | 19 Nov 2020 18:05:46 |
| User entered 'No (N)' | Samantha Wheeler (b) (4) | 18 Nov 2020 14:30:13 |
|                       | (b) (4)                  |                      |

US3762161

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:14:36

[Number of Days in ICU](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 19 Nov 2020 18:05:46 |
| User entered empty. | Samantha Wheeler (b) (4) | 18 Nov 2020 14:30:13 |
|                     | (b) (4)                  |                      |

US3762161

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:14:36

[Persistent or significant disability or incapacity](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 19 Nov 2020 18:05:46 |
| User entered '0'    | Samantha Wheeler (b) (4) | 18 Nov 2020 14:30:13 |
|                     | (b) (4)                  |                      |

US3762161

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:14:36

[Congenital anomaly or birth defect](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 19 Nov 2020 18:05:46 |
| User entered '0'    | Samantha Wheeler (b) (4) | 18 Nov 2020 14:30:13 |
|                     | (b) (4)                  |                      |

US3762161

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:14:36

[Other medically important event](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 19 Nov 2020 18:05:46 |
| User entered '0'    | Samantha Wheeler (b) (4) | 18 Nov 2020 14:30:13 |
|                     | (b) (4)                  |                      |

US3762161

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:14:36

[Relationship to investigational product](#)

| Audit                                    | User                     | Time (GMT)           |
|------------------------------------------|--------------------------|----------------------|
| DataPoint Verified.                      | (b) (4), (b) (6)         | 19 Nov 2020 18:05:46 |
| User entered 'Not Related (NOT RELATED)' | Samantha Wheeler (b) (4) | 18 Nov 2020 14:30:13 |
|                                          | (b) (4)                  |                      |



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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:14:36

[Relationship to Study Procedure](#)

| Audit                                    | User                     | Time (GMT)           |
|------------------------------------------|--------------------------|----------------------|
| DataPoint Verified.                      | (b) (4), (b) (6)         | 19 Nov 2020 18:05:46 |
| User entered 'Not Related (NOT RELATED)' | Samantha Wheeler (b) (4) | 18 Nov 2020 14:30:13 |
|                                          | (b) (4)                  |                      |

US3762161

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:14:36

Action taken with investigational product

| Audit                                                                                  | User                     | Time (GMT)           |
|----------------------------------------------------------------------------------------|--------------------------|----------------------|
| DataPoint Verified.                                                                    | (b) (4), (b) (6)         | 24 Nov 2020 19:12:41 |
| DataPoint Un-verified.                                                                 | (b) (4), (b) (6)         | 24 Nov 2020 19:08:46 |
| User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error     | (b) (4), (b) (6)         | 24 Nov 2020 19:08:46 |
| DataPoint Verified.                                                                    | (b) (4), (b) (6)         | 19 Nov 2020 18:05:46 |
| User closed query 'Data is required. Please complete.' (Site from System).             | System                   | 18 Nov 2020 14:31:05 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System                   | 18 Nov 2020 14:31:05 |
| User entered 'None (NONE)' reason for change: Data Entry Error                         | Samantha Wheeler (b) (4) | 18 Nov 2020 14:31:05 |
| User opened query 'Data is required. Please complete.' (Site from System).             | (b) (4)                  | 18 Nov 2020 14:30:13 |
| User entered empty.                                                                    | System                   | 18 Nov 2020 14:30:13 |
|                                                                                        | Samantha Wheeler (b) (4) | 18 Nov 2020 14:30:13 |
|                                                                                        | (b) (4)                  |                      |

US3762161

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:14:36

[None](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 19 Nov 2020 18:05:46 |
| User entered '1'    | Samantha Wheeler (b) (4) | 18 Nov 2020 14:30:13 |
|                     | (b) (4)                  |                      |

US3762161

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:14:36

[Concomitant Medication](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 19 Nov 2020 18:05:46 |
| User entered '0'    | Samantha Wheeler (b) (4) | 18 Nov 2020 14:30:13 |
|                     | (b) (4)                  |                      |

US3762161

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:14:36

[Concomitant Procedure](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 19 Nov 2020 18:05:46 |
| User entered '0'    | Samantha Wheeler (b) (4) | 18 Nov 2020 14:30:13 |
|                     | (b) (4)                  |                      |

**US3762161**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 26 Nov 2020 11:14:36**

[Outcome](#)

| Audit                                                  | User                     | Time (GMT)           |
|--------------------------------------------------------|--------------------------|----------------------|
| DataPoint Verified.                                    | (b) (4), (b) (6)         | 19 Nov 2020 18:05:46 |
| User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' | Samantha Wheeler (b) (4) | 18 Nov 2020 14:30:13 |
|                                                        | (b) (4)                  |                      |

US3762161

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:14:36

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 19 Nov 2020 18:05:46 |
| User entered empty. | Samantha Wheeler (b) (4) | 18 Nov 2020 14:30:13 |
|                     | (b) (4)                  |                      |

US3762161

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:14:36

[Narrative](#)

| Audit                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | User                                | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|----------------------|
| DataPoint Verified.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | (b) (4), (b) (6)                    | 19 Nov 2020 18:05:46 |
| User entered '74 Y/O MALE WHO RECEIVED SECOND DOSE OF PRODUCT ON 9/30 WITHOUT INCIDENT AND WAS SEEN FOR ROUTINE F/U ON 11/03 AND REPORTED NO SYMPTOMS WHO WAS ADMITTED TO WFBMC ON 11/10 WITH DIAGNOSIS OF GASTROENTERITIS WITH ASSOCIATED SEPSIS, ACUTE KIDNEY INJURY, AND POSSIBLE GI BLEED. HE HAD REPORTED FEELING TIRED WITH HEADACHES AND MUSCLE ACHES ON 11/09 AND WAS SEEN FOR A SICK VISIT. A PCR FOR COVID-19 WAS PERFORMED AT THE TIME WAS NEGATIVE. ON TELEPHONE F/U ON 11/10, HE REPORTED INCREASED FATIGUE AND DEVELOPMENT OF DIARRHEA WITH BLACK STOOL. WE RECOMMENDED GOING TO EDC (WHICH HAD ALSO BEEN RECOMMENDED BY PCP). HE WAS ADMITTED FROM THE ED AND DIAGNOSED AS ABOVE.' | Samantha Wheeler (b) (4)<br>(b) (4) | 18 Nov 2020 14:30:13 |



**US3762161**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 26 Nov 2020 11:14:36**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 18 Nov 2020 14:30:13 |

**US3762161**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 26 Nov 2020 11:14:36**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 18 Nov 2020 14:30:13 |

**US3762161**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 26 Nov 2020 11:14:36**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '0' | System | 18 Nov 2020 14:30:13 |

US3762161

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:14:36

[AEID](#)

| Audit                                                 | User             | Time (GMT)           |
|-------------------------------------------------------|------------------|----------------------|
| DataPoint Verified.                                   | (b) (4), (b) (6) | 19 Nov 2020 18:05:46 |
| Reviewed for Safety.                                  | (b) (4), (b) (6) | 18 Nov 2020 14:59:43 |
| User entered<br>'USA-US130-2020-mRNA-1273-P301000001' | (b) (4), (b) (6) | 18 Nov 2020 14:59:36 |

US3762161

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:14:36

[Adverse event](#)

| Audit                                                                                                                                                                                                          | User                                | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|----------------------|
| DataPoint Verified.                                                                                                                                                                                            | (b) (4), (b) (6)                    | 19 Nov 2020 18:05:46 |
| User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Electrolyte and fluid balance conditions, HLT: Total fluid volume decreased, PT: Dehydration, LLT: Dehydration - version MedDRA\\23.0. | Coder Import (b) (4)<br>(b) (4)     | 18 Nov 2020 14:46:06 |
| User coded data point as Term Coded data point by User: (b) (6) version MedDRA\\23.0.                                                                                                                          | Coder Import (b) (4)<br>(b) (4)     | 18 Nov 2020 14:46:06 |
| Data point term sent to Coder                                                                                                                                                                                  | System                              | 18 Nov 2020 14:35:11 |
| User entered '[Diarrhea with] Dehydration'                                                                                                                                                                     | Samantha Wheeler (b) (4)<br>(b) (4) | 18 Nov 2020 14:34:31 |

**US3762161**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 26 Nov 2020 11:14:36**

[Was this a medically-attended AE?](#)

| Audit                  | User                     | Time (GMT)           |
|------------------------|--------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)         | 19 Nov 2020 18:05:46 |
| User entered 'Yes (Y)' | Samantha Wheeler (b) (4) | 18 Nov 2020 14:34:31 |
|                        | (b) (4)                  |                      |

US3762161

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:14:36

[Was this a Solicited Adverse Reaction?](#)

| Audit                 | User                     | Time (GMT)           |
|-----------------------|--------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)         | 19 Nov 2020 18:05:46 |
| User entered 'No (N)' | Samantha Wheeler (b) (4) | 18 Nov 2020 14:34:31 |
|                       | (b) (4)                  |                      |

US3762161

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:14:36

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit                 | User                     | Time (GMT)           |
|-----------------------|--------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)         | 19 Nov 2020 18:05:46 |
| User entered 'No (N)' | Samantha Wheeler (b) (4) | 18 Nov 2020 14:34:31 |
|                       | (b) (4)                  |                      |



US3762161

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:14:36

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

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)         | 19 Nov 2020 18:05:46 |
| User entered '09 Nov 2020' | Samantha Wheeler (b) (4) | 18 Nov 2020 14:34:31 |
|                            | (b) (4)                  |                      |

US3762161

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:14:36

Start time (00:00-23:59)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 19 Nov 2020 18:05:46 |
| User entered empty. | Samantha Wheeler (b) (4) | 18 Nov 2020 14:34:31 |
|                     | (b) (4)                  |                      |

**US3762161**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 26 Nov 2020 11:14:36**

[AE start date and time \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 18 Nov 2020 14:34:31 |

US3762161

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:14:36

[Ongoing?](#)

| Audit                                                     | User                     | Time (GMT)           |
|-----------------------------------------------------------|--------------------------|----------------------|
| DataPoint Verified.                                       | (b) (4), (b) (6)         | 24 Nov 2020 19:18:16 |
| DataPoint Un-verified.                                    | Samantha Wheeler (b) (4) | 24 Nov 2020 19:17:37 |
| User entered 'No (N)' reason for change: Data Entry Error | (b) (4)                  | 24 Nov 2020 19:17:37 |
| DataPoint Verified.                                       | (b) (4), (b) (6)         | 19 Nov 2020 18:05:46 |
| User entered 'Yes (Y)'                                    | Samantha Wheeler (b) (4) | 18 Nov 2020 14:34:31 |

US3762161

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:14:36

If not Ongoing, end date (dd MMM yyyy)

| Audit                                                                                                                                                                       | User                     | Time (GMT)           |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|----------------------|
| DataPoint Verified.                                                                                                                                                         | (b) (4), (b) (6)         | 24 Nov 2020 19:18:16 |
| User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).             | System                   | 24 Nov 2020 19:18:05 |
| Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System). | System                   | 24 Nov 2020 19:18:05 |
| User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).             | System                   | 24 Nov 2020 19:17:37 |
| DataPoint Un-verified.                                                                                                                                                      | Samantha Wheeler (b) (4) | 24 Nov 2020 19:17:37 |
| User entered '15 Nov 2020' reason for change: Data Entry Error                                                                                                              | Samantha Wheeler (b) (4) | 24 Nov 2020 19:17:37 |
| DataPoint Verified.                                                                                                                                                         | (b) (4), (b) (6)         | 19 Nov 2020 18:05:46 |
| User entered empty.                                                                                                                                                         | Samantha Wheeler (b) (4) | 18 Nov 2020 14:34:31 |

US3762161

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:14:36

End time (00:00-23:59)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 19 Nov 2020 18:05:46 |
| User entered empty. | Samantha Wheeler (b) (4) | 18 Nov 2020 14:34:31 |
|                     | (b) (4)                  |                      |

**US3762161**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 26 Nov 2020 11:14:36**

[AE End Date and Time \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 18 Nov 2020 14:34:31 |

US3762161

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:14:36

[Severity](#)

| Audit                                              | User                     | Time (GMT)           |
|----------------------------------------------------|--------------------------|----------------------|
| DataPoint Verified.                                | (b) (4), (b) (6)         | 19 Nov 2020 18:05:46 |
| User entered 'Grade 2/Moderate (Grade 2/Moderate)' | Samantha Wheeler (b) (4) | 18 Nov 2020 14:34:31 |
|                                                    | (b) (4)                  |                      |



US3762161

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:14:36

[Is the adverse event serious?](#)

| Audit                  | User                     | Time (GMT)           |
|------------------------|--------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)         | 19 Nov 2020 18:05:46 |
| User entered 'Yes (Y)' | Samantha Wheeler (b) (4) | 18 Nov 2020 14:34:31 |
|                        | (b) (4)                  |                      |

US3762161

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:14:36

[Death](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 19 Nov 2020 18:05:46 |
| User entered '0'    | Samantha Wheeler (b) (4) | 18 Nov 2020 14:34:31 |
|                     | (b) (4)                  |                      |

US3762161

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:14:36

[Life threatening](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 19 Nov 2020 18:05:46 |
| User entered '0'    | Samantha Wheeler (b) (4) | 18 Nov 2020 14:34:31 |
|                     | (b) (4)                  |                      |

US3762161

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:14:36

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 19 Nov 2020 18:05:46 |
| User entered '1'    | Samantha Wheeler (b) (4) | 18 Nov 2020 14:34:31 |
|                     | (b) (4)                  |                      |

US3762161

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:14:36

Hospital Admission Date (*dd MMM yyyy*)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)         | 19 Nov 2020 18:05:46 |
| User entered '10 Nov 2020' | Samantha Wheeler (b) (4) | 18 Nov 2020 14:34:31 |
|                            | (b) (4)                  |                      |

US3762161

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:14:36

Hospital Discharge Date (dd MMM yyyy)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)         | 19 Nov 2020 18:05:46 |
| User entered '15 Nov 2020' | Samantha Wheeler (b) (4) | 18 Nov 2020 14:34:31 |
|                            | (b) (4)                  |                      |

US3762161

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:14:36

[Admitted to ICU?](#)

| Audit                 | User                     | Time (GMT)           |
|-----------------------|--------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)         | 19 Nov 2020 18:05:46 |
| User entered 'No (N)' | Samantha Wheeler (b) (4) | 18 Nov 2020 14:34:31 |
|                       | (b) (4)                  |                      |

US3762161

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:14:36

[Number of Days in ICU](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 19 Nov 2020 18:05:46 |
| User entered empty. | Samantha Wheeler (b) (4) | 18 Nov 2020 14:34:31 |
|                     | (b) (4)                  |                      |



US3762161

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:14:36

[Persistent or significant disability or incapacity](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 19 Nov 2020 18:05:46 |
| User entered '0'    | Samantha Wheeler (b) (4) | 18 Nov 2020 14:34:31 |
|                     | (b) (4)                  |                      |

US3762161

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:14:36

[Congenital anomaly or birth defect](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 19 Nov 2020 18:05:46 |
| User entered '0'    | Samantha Wheeler (b) (4) | 18 Nov 2020 14:34:31 |
|                     | (b) (4)                  |                      |

US3762161

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:14:36

[Other medically important event](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 19 Nov 2020 18:05:46 |
| User entered '0'    | Samantha Wheeler (b) (4) | 18 Nov 2020 14:34:31 |
|                     | (b) (4)                  |                      |

US3762161

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:14:36

[Relationship to investigational product](#)

| Audit                                    | User                     | Time (GMT)           |
|------------------------------------------|--------------------------|----------------------|
| DataPoint Verified.                      | (b) (4), (b) (6)         | 19 Nov 2020 18:05:46 |
| User entered 'Not Related (NOT RELATED)' | Samantha Wheeler (b) (4) | 18 Nov 2020 14:34:31 |
|                                          | (b) (4)                  |                      |

US3762161

**Folder:** Adverse Events

**Form:** Adverse Events (7)

**Generated On:** 26 Nov 2020 11:14:36

[Relationship to Study Procedure](#)

| Audit                                    | User                     | Time (GMT)           |
|------------------------------------------|--------------------------|----------------------|
| DataPoint Verified.                      | (b) (4), (b) (6)         | 19 Nov 2020 18:05:46 |
| User entered 'Not Related (NOT RELATED)' | Samantha Wheeler (b) (4) | 18 Nov 2020 14:34:31 |
|                                          | (b) (4)                  |                      |

US3762161

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:14:36

[Action taken with investigational product](#)

| Audit                                          | User                     | Time (GMT)           |
|------------------------------------------------|--------------------------|----------------------|
| DataPoint Verified.                            | (b) (4), (b) (6)         | 24 Nov 2020 19:12:41 |
| DataPoint Un-verified.                         | (b) (4), (b) (6)         | 24 Nov 2020 19:09:26 |
| User entered 'Not Applicable (NOT APPLICABLE)' | (b) (4), (b) (6)         | 24 Nov 2020 19:09:26 |
| reason for change: Data Entry Error            |                          |                      |
| DataPoint Verified.                            | (b) (4), (b) (6)         | 19 Nov 2020 18:05:46 |
| User entered 'None (NONE)'                     | Samantha Wheeler (b) (4) | 18 Nov 2020 14:34:31 |
|                                                | (b) (4)                  |                      |

US3762161

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:14:36

[None](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 19 Nov 2020 18:05:46 |
| User entered '1'    | Samantha Wheeler (b) (4) | 18 Nov 2020 14:34:31 |
|                     | (b) (4)                  |                      |

US3762161

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:14:36

[Concomitant Medication](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 19 Nov 2020 18:05:46 |
| User entered '0'    | Samantha Wheeler (b) (4) | 18 Nov 2020 14:34:31 |
|                     | (b) (4)                  |                      |



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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:14:36

[Concomitant Procedure](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 19 Nov 2020 18:05:46 |
| User entered '0'    | Samantha Wheeler (b) (4) | 18 Nov 2020 14:34:31 |
|                     | (b) (4)                  |                      |

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:14:36

[Outcome](#)

| Audit                                                                                  | User                     | Time (GMT)           |
|----------------------------------------------------------------------------------------|--------------------------|----------------------|
| DataPoint Verified.                                                                    | (b) (4), (b) (6)         | 24 Nov 2020 19:18:16 |
| DataPoint Un-verified.                                                                 | Samantha Wheeler (b) (4) | 24 Nov 2020 19:18:05 |
| User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:              | (b) (4)                  |                      |
| Data Entry Error                                                                       | Samantha Wheeler (b) (4) | 24 Nov 2020 19:18:05 |
| DataPoint Verified.                                                                    | (b) (4)                  |                      |
| DataPoint Verified.                                                                    | (b) (4), (b) (6)         | 19 Nov 2020 18:05:46 |
| User closed query 'Data is required. Please complete.' (Site from System).             | System                   | 18 Nov 2020 14:34:51 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System                   | 18 Nov 2020 14:34:51 |
| User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change:          | Samantha Wheeler (b) (4) | 18 Nov 2020 14:34:51 |
| Data Entry Error                                                                       | (b) (4)                  |                      |
| User opened query 'Data is required. Please complete.' (Site from System).             | System                   | 18 Nov 2020 14:34:31 |
| User entered empty.                                                                    | Samantha Wheeler (b) (4) | 18 Nov 2020 14:34:31 |
|                                                                                        | (b) (4)                  |                      |

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:14:36

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 19 Nov 2020 18:05:46 |
| User entered empty. | Samantha Wheeler (b) (4) | 18 Nov 2020 14:34:31 |
|                     | (b) (4)                  |                      |

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:14:36

[Narrative](#)

| Audit                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | User                                | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|----------------------|
| DataPoint Verified.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | (b) (4), (b) (6)                    | 19 Nov 2020 18:05:46 |
| User entered '74 Y/O MALE WHO RECEIVED SECOND DOSE OF PRODUCT ON 9/30 WITHOUT INCIDENT AND WAS SEEN FOR ROUTINE F/U ON 11/03 AND REPORTED NO SYMPTOMS WHO WAS ADMITTED TO WFBMC ON 11/10 WITH DIAGNOSIS OF GASTROENTERITIS WITH ASSOCIATED SEPSIS, ACUTE KIDNEY INJURY, AND POSSIBLE GI BLEED. HE HAD REPORTED FEELING TIRED WITH HEADACHES AND MUSCLE ACHES ON 11/09 AND WAS SEEN FOR A SICK VISIT. A PCR FOR COVID-19 WAS PERFORMED AT THE TIME WAS NEGATIVE. ON TELEPHONE F/U ON 11/10, HE REPORTED INCREASED FATIGUE AND DEVELOPMENT OF DIARRHEA WITH BLACK STOOL. WE RECOMMENDED GOING TO EDC (WHICH HAD ALSO BEEN RECOMMENDED BY PCP). HE WAS ADMITTED FROM THE ED AND DIAGNOSED AS ABOVE.' | Samantha Wheeler (b) (4)<br>(b) (4) | 18 Nov 2020 14:34:31 |

**US3762161**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 26 Nov 2020 11:14:36**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 18 Nov 2020 14:34:31 |

**US3762161**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 26 Nov 2020 11:14:36**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 18 Nov 2020 14:34:31 |

**US3762161**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 26 Nov 2020 11:14:36**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '0' | System | 18 Nov 2020 14:34:31 |

US3762161

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 11:14:36

[Adverse event](#)

| Audit                                                                                                                                                                                                                 | User                     | Time (GMT)           |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|----------------------|
| DataPoint Verified.                                                                                                                                                                                                   | (b) (4), (b) (6)         | 24 Nov 2020 20:10:53 |
| User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Abdominal and gastrointestinal infections, PT: Gastroenteritis, LLT: Gastroenteritis - version MedDRA\\23.0. | Coder Import (b) (4)     | 24 Nov 2020 19:35:08 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.                                                                                                                          | Coder Import (b) (4)     | 24 Nov 2020 19:35:08 |
| Data point term sent to Coder                                                                                                                                                                                         | System                   | 24 Nov 2020 19:34:19 |
| User entered 'gastroenteritis'                                                                                                                                                                                        | Samantha Wheeler (b) (4) | 24 Nov 2020 19:33:29 |
|                                                                                                                                                                                                                       | (b) (4)                  |                      |



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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 11:14:36

[Was this a medically-attended AE?](#)

| Audit                  | User                     | Time (GMT)           |
|------------------------|--------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)         | 24 Nov 2020 20:10:53 |
| User entered 'Yes (Y)' | Samantha Wheeler (b) (4) | 24 Nov 2020 19:33:29 |
|                        | (b) (4)                  |                      |

US3762161

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 11:14:36

[Was this a Solicited Adverse Reaction?](#)

| Audit                 | User                     | Time (GMT)           |
|-----------------------|--------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)         | 24 Nov 2020 20:10:53 |
| User entered 'No (N)' | Samantha Wheeler (b) (4) | 24 Nov 2020 19:33:29 |
|                       | (b) (4)                  |                      |

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 11:14:36

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit                 | User                     | Time (GMT)           |
|-----------------------|--------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)         | 24 Nov 2020 20:10:53 |
| User entered 'No (N)' | Samantha Wheeler (b) (4) | 24 Nov 2020 19:33:29 |
|                       | (b) (4)                  |                      |

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 11:14:36

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

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)         | 24 Nov 2020 20:10:53 |
| User entered '10 Nov 2020' | Samantha Wheeler (b) (4) | 24 Nov 2020 19:33:29 |
|                            | (b) (4)                  |                      |

US3762161

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 11:14:36

[Start time \(00:00-23:59\)](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 24 Nov 2020 20:10:53 |
| User entered empty. | Samantha Wheeler (b) (4) | 24 Nov 2020 19:33:29 |
|                     | (b) (4)                  |                      |

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 11:14:36

[AE start date and time \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 24 Nov 2020 19:33:29 |

US3762161

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 11:14:36

[Ongoing?](#)

| Audit                 | User                     | Time (GMT)           |
|-----------------------|--------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)         | 24 Nov 2020 20:10:53 |
| User entered 'No (N)' | Samantha Wheeler (b) (4) | 24 Nov 2020 19:33:29 |
|                       | (b) (4)                  |                      |

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 11:14:36

If not Ongoing, end date (dd MMM yyyy)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)         | 24 Nov 2020 20:10:53 |
| User entered '15 Nov 2020' | Samantha Wheeler (b) (4) | 24 Nov 2020 19:33:29 |
|                            | (b) (4)                  |                      |



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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 11:14:36

End time (00:00-23:59)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 24 Nov 2020 20:10:53 |
| User entered empty. | Samantha Wheeler (b) (4) | 24 Nov 2020 19:33:29 |
|                     | (b) (4)                  |                      |

**US3762161**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 26 Nov 2020 11:14:36**

[AE End Date and Time \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 24 Nov 2020 19:33:29 |

US3762161

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 11:14:36

[Severity](#)

| Audit                                              | User                     | Time (GMT)           |
|----------------------------------------------------|--------------------------|----------------------|
| DataPoint Verified.                                | (b) (4), (b) (6)         | 24 Nov 2020 20:10:53 |
| User entered 'Grade 2/Moderate (Grade 2/Moderate)' | Samantha Wheeler (b) (4) | 24 Nov 2020 19:33:29 |
|                                                    | (b) (4)                  |                      |

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 11:14:36

[Is the adverse event serious?](#)

| Audit                  | User                     | Time (GMT)           |
|------------------------|--------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)         | 24 Nov 2020 20:10:53 |
| User entered 'Yes (Y)' | Samantha Wheeler (b) (4) | 24 Nov 2020 19:33:29 |
|                        | (b) (4)                  |                      |

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 11:14:36

[Death](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 24 Nov 2020 20:10:53 |
| User entered '0'    | Samantha Wheeler (b) (4) | 24 Nov 2020 19:33:29 |
|                     | (b) (4)                  |                      |

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 11:14:36

[Life threatening](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 24 Nov 2020 20:10:53 |
| User entered '0'    | Samantha Wheeler (b) (4) | 24 Nov 2020 19:33:29 |
|                     | (b) (4)                  |                      |

US3762161

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 11:14:36

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 24 Nov 2020 20:10:53 |
| User entered '1'    | Samantha Wheeler (b) (4) | 24 Nov 2020 19:33:29 |
|                     | (b) (4)                  |                      |

US3762161

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 11:14:36

Hospital Admission Date (*dd MMM yyyy*)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)         | 24 Nov 2020 20:10:53 |
| User entered '10 Nov 2020' | Samantha Wheeler (b) (4) | 24 Nov 2020 19:33:29 |
|                            | (b) (4)                  |                      |



US3762161

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 11:14:36

Hospital Discharge Date (*dd MMM yyyy*)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)         | 24 Nov 2020 20:10:53 |
| User entered '15 Nov 2020' | Samantha Wheeler (b) (4) | 24 Nov 2020 19:33:29 |
|                            | (b) (4)                  |                      |

US3762161

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 11:14:36

[Admitted to ICU?](#)

| Audit                 | User                     | Time (GMT)           |
|-----------------------|--------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)         | 24 Nov 2020 20:10:53 |
| User entered 'No (N)' | Samantha Wheeler (b) (4) | 24 Nov 2020 19:33:29 |
|                       | (b) (4)                  |                      |

US3762161

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 11:14:36

[Number of Days in ICU](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 24 Nov 2020 20:10:53 |
| User entered empty. | Samantha Wheeler (b) (4) | 24 Nov 2020 19:33:29 |
|                     | (b) (4)                  |                      |

US3762161

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 11:14:36

[Persistent or significant disability or incapacity](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 24 Nov 2020 20:10:53 |
| User entered '0'    | Samantha Wheeler (b) (4) | 24 Nov 2020 19:33:29 |
|                     | (b) (4)                  |                      |

US3762161

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 11:14:36

[Congenital anomaly or birth defect](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 24 Nov 2020 20:10:53 |
| User entered '0'    | Samantha Wheeler (b) (4) | 24 Nov 2020 19:33:29 |
|                     | (b) (4)                  |                      |

US3762161

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 11:14:36

[Other medically important event](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 24 Nov 2020 20:10:53 |
| User entered '0'    | Samantha Wheeler (b) (4) | 24 Nov 2020 19:33:29 |
|                     | (b) (4)                  |                      |

US3762161

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 11:14:36

[Relationship to investigational product](#)

| Audit                                    | User                     | Time (GMT)           |
|------------------------------------------|--------------------------|----------------------|
| DataPoint Verified.                      | (b) (4), (b) (6)         | 24 Nov 2020 20:10:53 |
| User entered 'Not Related (NOT RELATED)' | Samantha Wheeler (b) (4) | 24 Nov 2020 19:33:29 |
|                                          | (b) (4)                  |                      |

US3762161

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 11:14:36

[Relationship to Study Procedure](#)

| Audit                                    | User                     | Time (GMT)           |
|------------------------------------------|--------------------------|----------------------|
| DataPoint Verified.                      | (b) (4), (b) (6)         | 24 Nov 2020 20:10:53 |
| User entered 'Not Related (NOT RELATED)' | Samantha Wheeler (b) (4) | 24 Nov 2020 19:33:29 |
|                                          | (b) (4)                  |                      |



US3762161

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 11:14:36

[Action taken with investigational product](#)

| Audit                                          | User                     | Time (GMT)           |
|------------------------------------------------|--------------------------|----------------------|
| DataPoint Verified.                            | (b) (4), (b) (6)         | 24 Nov 2020 20:26:41 |
| DataPoint Un-verified.                         | Samantha Wheeler (b) (4) | 24 Nov 2020 20:15:14 |
| User entered 'Not Applicable (NOT APPLICABLE)' | (b) (4)                  |                      |
| reason for change: Data Entry Error            | Samantha Wheeler (b) (4) | 24 Nov 2020 20:15:14 |
| DataPoint Verified.                            | (b) (4)                  |                      |
|                                                | (b) (4), (b) (6)         | 24 Nov 2020 20:10:53 |
| User entered 'None (NONE)'                     | Samantha Wheeler (b) (4) | 24 Nov 2020 19:33:29 |
|                                                | (b) (4)                  |                      |

US3762161

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 11:14:36

[None](#)

| Audit                                                                                                                              | User                     | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------------------------------|--------------------------|----------------------|
| DataPoint Verified.                                                                                                                | (b) (4), (b) (6)         | 24 Nov 2020 20:10:53 |
| User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System). | System                   | 24 Nov 2020 19:34:12 |
| User entered '1' reason for change: Data Entry Error                                                                               | Samantha Wheeler (b) (4) | 24 Nov 2020 19:34:12 |
| User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System). | (b) (4)                  | 24 Nov 2020 19:33:29 |
| User entered '0'                                                                                                                   | System                   | 24 Nov 2020 19:33:29 |
|                                                                                                                                    | Samantha Wheeler (b) (4) | 24 Nov 2020 19:33:29 |
|                                                                                                                                    | (b) (4)                  |                      |

US3762161

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 11:14:36

[Concomitant Medication](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 24 Nov 2020 20:10:53 |
| User entered '0'    | Samantha Wheeler (b) (4) | 24 Nov 2020 19:33:29 |
|                     | (b) (4)                  |                      |

US3762161

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 11:14:36

[Concomitant Procedure](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 24 Nov 2020 20:10:53 |
| User entered '0'    | Samantha Wheeler (b) (4) | 24 Nov 2020 19:33:29 |
|                     | (b) (4)                  |                      |

US3762161

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 11:14:36

[Outcome](#)

| Audit                                                  | User                     | Time (GMT)           |
|--------------------------------------------------------|--------------------------|----------------------|
| DataPoint Verified.                                    | (b) (4), (b) (6)         | 24 Nov 2020 20:10:53 |
| User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' | Samantha Wheeler (b) (4) | 24 Nov 2020 19:33:29 |
|                                                        | (b) (4)                  |                      |

US3762161

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 11:14:36

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 24 Nov 2020 20:10:53 |
| User entered empty. | Samantha Wheeler (b) (4) | 24 Nov 2020 19:33:29 |
|                     | (b) (4)                  |                      |

US3762161

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 11:14:36

[Narrative](#)

| Audit                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | User                     | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|----------------------|
| DataPoint Verified.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | (b) (4), (b) (6)         | 24 Nov 2020 20:26:41 |
| DataPoint Un-verified.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | Samantha Wheeler (b) (4) | 24 Nov 2020 20:14:05 |
| User entered '74 Y/O MALE WHO RECEIVED SECOND DOSE OF PRODUCT ON 9/30 WITHOUT INCIDENT AND WAS SEEN FOR ROUTINE F/U ON 11/03 AND REPORTED NO SYMPTOMS WHO WAS ADMITTED TO WFBMC ON 11/10 WITH DIAGNOSIS OF GASTROENTERITIS WITH ASSOCIATED SEPSIS, ACUTE KIDNEY INJURY, AND POSSIBLE GI BLEED. HE HAD REPORTED FEELING TIRED WITH HEADACHES AND MUSCLE ACHES ON 11/09 AND WAS SEEN FOR A SICK VISIT. A PCR FOR COVID-19 WAS PERFORMED AT THE TIME WAS NEGATIVE. ON TELEPHONE F/U ON 11/10, HE REPORTED INCREASED FATIGUE AND DEVELOPMENT OF DIARRHEA WITH BLACK STOOL. WE RECOMMENDED GOING TO EDC (WHICH HAD ALSO BEEN RECOMMENDED BY PCP). HE WAS ADMITTED FROM THE ED AND DIAGNOSED AS ABOVE. | Samantha Wheeler (b) (4) | 24 Nov 2020 20:14:05 |
| ct abdomen/pelvis with contrast' reason for change:                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |                          |                      |
| Data Entry Error                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                          |                      |
| DataPoint Verified.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | (b) (4), (b) (6)         | 24 Nov 2020 20:10:53 |
| User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | System                   | 24 Nov 2020 19:34:12 |
| Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | System                   | 24 Nov 2020 19:34:12 |

US3762161

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 11:14:36

[Narrative](#)

| Audit                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | User                     | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|----------------------|
| User entered '74 Y/O MALE WHO RECEIVED SECOND DOSE OF PRODUCT ON 9/30 WITHOUT INCIDENT AND WAS SEEN FOR ROUTINE F/U ON 11/03 AND REPORTED NO SYMPTOMS WHO WAS ADMITTED TO WFBMC ON 11/10 WITH DIAGNOSIS OF GASTROENTERITIS WITH ASSOCIATED SEPSIS, ACUTE KIDNEY INJURY, AND POSSIBLE GI BLEED. HE HAD REPORTED FEELING TIRED WITH HEADACHES AND MUSCLE ACHES ON 11/09 AND WAS SEEN FOR A SICK VISIT. A PCR FOR COVID-19 WAS PERFORMED AT THE TIME WAS NEGATIVE. ON TELEPHONE F/U ON 11/10, HE REPORTED INCREASED FATIGUE AND DEVELOPMENT OF DIARRHEA WITH BLACK STOOL. WE RECOMMENDED GOING TO EDC (WHICH HAD ALSO BEEN RECOMMENDED BY PCP). HE WAS ADMITTED FROM THE ED AND DIAGNOSED AS ABOVE.' reason for change: Data Entry Error | Samantha Wheeler (b) (4) | 24 Nov 2020 19:34:12 |
| User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | System                   | 24 Nov 2020 19:33:29 |
| User entered empty.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | Samantha Wheeler (b) (4) | 24 Nov 2020 19:33:29 |



**US3762161**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 26 Nov 2020 11:14:36**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 24 Nov 2020 19:33:29 |

**US3762161**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 26 Nov 2020 11:14:36**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 24 Nov 2020 19:33:29 |

**US3762161**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 26 Nov 2020 11:14:36**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '0' | System | 24 Nov 2020 19:33:29 |

US3762161

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

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

**Generated On: 26 Nov 2020 11:14:36**

[Were any prior/concomitant medications and/or vaccinations taken?](#)

| Audit                  | User                          | Time (GMT)           |
|------------------------|-------------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)              | 18 Nov 2020 16:13:08 |
| User entered 'Yes (Y)' | Kaitlyn Van Leuvan<br>(b) (4) | 03 Nov 2020 17:52:58 |

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:14:36

[Name of Medication](#)

| Audit                                                                                                                                                                                                                                       | User                            | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------|----------------------|
| DataPoint Verified.                                                                                                                                                                                                                         | (b) (4), (b) (6)                | 18 Nov 2020 16:15:10 |
| User coded data point as ATC:<br>CARDIOVASCULAR SYSTEM, ATC: AGENTS<br>ACTING ON THE RENIN-ANGIOTENSIN<br>SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC:<br>ACE INHIBITORS, PLAIN, PRODUCT:<br>LISINOPRIL - version<br>WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4) | 03 Nov 2020 18:36:23 |
| 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) | 03 Nov 2020 18:36:23 |
| Data point term sent to Coder                                                                                                                                                                                                               | System                          | 03 Nov 2020 17:54:32 |
| User entered 'Lisinopril'                                                                                                                                                                                                                   | Kaitlyn Van Leuvan<br>(b) (4)   | 03 Nov 2020 17:53:59 |

US3762161

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

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 11:14:36**

[Prophylaxis](#)

| Audit                  | User                          | Time (GMT)           |
|------------------------|-------------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)              | 18 Nov 2020 16:15:10 |
| User entered 'Yes (Y)' | Kaitlyn Van Leuvan<br>(b) (4) | 03 Nov 2020 17:53:59 |

US3762161

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

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 11:14:36**

[Indication](#)

| Audit                           | User                          | Time (GMT)           |
|---------------------------------|-------------------------------|----------------------|
| DataPoint Verified.             | (b) (4), (b) (6)              | 18 Nov 2020 16:15:10 |
| User entered 'High cholesterol' | Kaitlyn Van Leuvan<br>(b) (4) | 03 Nov 2020 17:53:59 |

US3762161

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

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 11:14:36**

[Dose per administration](#)

| Audit               | User                          | Time (GMT)           |
|---------------------|-------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)              | 18 Nov 2020 16:15:10 |
| User entered '10'   | Kaitlyn Van Leuvan<br>(b) (4) | 03 Nov 2020 17:53:59 |



US3762161

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

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 11:14:36**

[Dose unit](#)

| Audit                  | User                          | Time (GMT)           |
|------------------------|-------------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)              | 18 Nov 2020 16:15:10 |
| User entered 'mg (mg)' | Kaitlyn Van Leuvan<br>(b) (4) | 03 Nov 2020 17:53:59 |

US3762161

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

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 11:14:36**

[If dose unit is Other, specify](#)

| Audit               | User                          | Time (GMT)           |
|---------------------|-------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)              | 18 Nov 2020 16:15:10 |
| User entered empty. | Kaitlyn Van Leuvan<br>(b) (4) | 03 Nov 2020 17:53:59 |

US3762161

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

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 11:14:36**

[Frequency](#)

| Audit                          | User                          | Time (GMT)           |
|--------------------------------|-------------------------------|----------------------|
| DataPoint Verified.            | (b) (4), (b) (6)              | 18 Nov 2020 16:15:10 |
| User entered 'once daily (QD)' | Kaitlyn Van Leuvan<br>(b) (4) | 03 Nov 2020 17:53:59 |

US3762161

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

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 11:14:36**

[If frequency is Other, specify](#)

| Audit               | User                          | Time (GMT)           |
|---------------------|-------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)              | 18 Nov 2020 16:15:10 |
| User entered empty. | Kaitlyn Van Leuvan<br>(b) (4) | 03 Nov 2020 17:53:59 |

US3762161

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

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 11:14:36**

[Route of administration](#)

| Audit                      | User                          | Time (GMT)           |
|----------------------------|-------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)              | 18 Nov 2020 16:15:10 |
| User entered 'Oral (ORAL)' | Kaitlyn Van Leuvan<br>(b) (4) | 03 Nov 2020 17:53:59 |

US3762161

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

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 11:14:36**

If route of administration is Other, specify

| Audit               | User                          | Time (GMT)           |
|---------------------|-------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)              | 18 Nov 2020 16:15:10 |
| User entered empty. | Kaitlyn Van Leuvan<br>(b) (4) | 03 Nov 2020 17:53:59 |

US3762161

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

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 11:14:36**

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

| Audit                      | User                          | Time (GMT)           |
|----------------------------|-------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)              | 18 Nov 2020 16:15:10 |
| User entered 'un Aug 2000' | Kaitlyn Van Leuvan<br>(b) (4) | 03 Nov 2020 17:53:59 |

US3762161

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

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 11:14:36**

[Start date completely unknown](#)

| Audit               | User                          | Time (GMT)           |
|---------------------|-------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)              | 18 Nov 2020 16:15:10 |
| User entered '0'    | Kaitlyn Van Leuvan<br>(b) (4) | 03 Nov 2020 17:53:59 |



US3762161

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

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 11:14:36**

[Ongoing?](#)

| Audit                  | User                          | Time (GMT)           |
|------------------------|-------------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)              | 18 Nov 2020 16:15:10 |
| User entered 'Yes (Y)' | Kaitlyn Van Leuvan<br>(b) (4) | 03 Nov 2020 17:53:59 |

US3762161

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

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 11:14:36**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit               | User                          | Time (GMT)           |
|---------------------|-------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)              | 18 Nov 2020 16:15:10 |
| User entered empty. | Kaitlyn Van Leuvan<br>(b) (4) | 03 Nov 2020 17:53:59 |

US3762161

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

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 11:14:36**

[Was this medication taken for solicited event?](#)

| Audit                 | User                          | Time (GMT)           |
|-----------------------|-------------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)              | 18 Nov 2020 16:15:10 |
| User entered 'No (N)' | Kaitlyn Van Leuvan<br>(b) (4) | 03 Nov 2020 17:53:59 |

US3762161

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

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 11:14:36**

[Separate Dosage Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 03 Nov 2020 17:53:59 |

US3762161

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

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 11:14:36**

[Interval Dosage Unit Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 03 Nov 2020 17:53:59 |

US3762161

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

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 11:14:36**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User   | Time (GMT)           |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 03 Nov 2020 17:53:59 |

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:14:36

[Name of Medication](#)

| Audit                                                                                                                                                                                                                              | User                            | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------|----------------------|
| DataPoint Verified.                                                                                                                                                                                                                | (b) (4), (b) (6)                | 18 Nov 2020 16:15:10 |
| User coded data point as ATC:<br>CARDIOVASCULAR SYSTEM, ATC: LIPID<br>MODIFYING AGENTS, ATC: LIPID MODIFYING<br>AGENTS, PLAIN, ATC: HMG COA REDUCTASE<br>INHIBITORS, PRODUCT: ATORVASTATIN -<br>version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4) | 03 Nov 2020 17:56:26 |
| User coded data point as Term Coded data point by<br>User: Coder System - version<br>WHODrug-Global-B3\\202003.                                                                                                                    | Coder Import (b) (4)<br>(b) (4) | 03 Nov 2020 17:56:26 |
| Data point term sent to Coder                                                                                                                                                                                                      | System                          | 03 Nov 2020 17:55:34 |
| User entered 'Atorvastatin'                                                                                                                                                                                                        | Kaitlyn Van Leuvan<br>(b) (4)   | 03 Nov 2020 17:55:02 |

US3762161

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

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 11:14:36**

[Prophylaxis](#)

| Audit                 | User                          | Time (GMT)           |
|-----------------------|-------------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)              | 18 Nov 2020 16:15:10 |
| User entered 'No (N)' | Kaitlyn Van Leuvan<br>(b) (4) | 03 Nov 2020 17:55:02 |



US3762161

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

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 11:14:36**

[Indication](#)

| Audit                           | User                          | Time (GMT)           |
|---------------------------------|-------------------------------|----------------------|
| DataPoint Verified.             | (b) (4), (b) (6)              | 18 Nov 2020 16:15:10 |
| User entered 'High cholesterol' | Kaitlyn Van Leuvan<br>(b) (4) | 03 Nov 2020 17:55:02 |

US3762161

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

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 11:14:36**

[Dose per administration](#)

| Audit               | User                          | Time (GMT)           |
|---------------------|-------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)              | 18 Nov 2020 16:15:10 |
| User entered '80'   | Kaitlyn Van Leuvan<br>(b) (4) | 03 Nov 2020 17:55:02 |

US3762161

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

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 11:14:36**

[Dose unit](#)

| Audit                  | User                          | Time (GMT)           |
|------------------------|-------------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)              | 18 Nov 2020 16:15:10 |
| User entered 'mg (mg)' | Kaitlyn Van Leuvan<br>(b) (4) | 03 Nov 2020 17:55:02 |

US3762161

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

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 11:14:36**

If dose unit is Other, specify

| Audit               | User                          | Time (GMT)           |
|---------------------|-------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)              | 18 Nov 2020 16:15:10 |
| User entered empty. | Kaitlyn Van Leuvan<br>(b) (4) | 03 Nov 2020 17:55:02 |

US3762161

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

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 11:14:36**

[Frequency](#)

| Audit                          | User                          | Time (GMT)           |
|--------------------------------|-------------------------------|----------------------|
| DataPoint Verified.            | (b) (4), (b) (6)              | 18 Nov 2020 16:15:10 |
| User entered 'once daily (QD)' | Kaitlyn Van Leuvan<br>(b) (4) | 03 Nov 2020 17:55:02 |

US3762161

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

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 11:14:36**

[If frequency is Other, specify](#)

| Audit               | User                          | Time (GMT)           |
|---------------------|-------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)              | 18 Nov 2020 16:15:10 |
| User entered empty. | Kaitlyn Van Leuvan<br>(b) (4) | 03 Nov 2020 17:55:02 |

US3762161

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

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 11:14:36**

[Route of administration](#)

| Audit                      | User                          | Time (GMT)           |
|----------------------------|-------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)              | 18 Nov 2020 16:15:10 |
| User entered 'Oral (ORAL)' | Kaitlyn Van Leuvan<br>(b) (4) | 03 Nov 2020 17:55:02 |

US3762161

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

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 11:14:36**

If route of administration is Other, specify

| Audit               | User                          | Time (GMT)           |
|---------------------|-------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)              | 18 Nov 2020 16:15:10 |
| User entered empty. | Kaitlyn Van Leuvan<br>(b) (4) | 03 Nov 2020 17:55:02 |



US3762161

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

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 11:14:36**

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

| Audit                                                          | User                          | Time (GMT)           |
|----------------------------------------------------------------|-------------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)              | 18 Nov 2020 16:15:10 |
| User entered 'UN Feb 2007' reason for change: Data Entry Error | Kaitlyn Van Leuvan<br>(b) (4) | 03 Nov 2020 17:57:40 |
| User entered 'un Feb 2017'                                     | Kaitlyn Van Leuvan<br>(b) (4) | 03 Nov 2020 17:55:02 |

US3762161

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

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 11:14:36**

[Start date completely unknown](#)

| Audit               | User                          | Time (GMT)           |
|---------------------|-------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)              | 18 Nov 2020 16:15:10 |
| User entered '0'    | Kaitlyn Van Leuvan<br>(b) (4) | 03 Nov 2020 17:55:02 |

US3762161

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

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 11:14:36**

[Ongoing?](#)

| Audit                  | User                          | Time (GMT)           |
|------------------------|-------------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)              | 18 Nov 2020 16:15:10 |
| User entered 'Yes (Y)' | Kaitlyn Van Leuvan<br>(b) (4) | 03 Nov 2020 17:55:02 |

US3762161

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

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 11:14:36**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit               | User                          | Time (GMT)           |
|---------------------|-------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)              | 18 Nov 2020 16:15:10 |
| User entered empty. | Kaitlyn Van Leuvan<br>(b) (4) | 03 Nov 2020 17:55:02 |

US3762161

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

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 11:14:36**

[Was this medication taken for solicited event?](#)

| Audit                 | User                          | Time (GMT)           |
|-----------------------|-------------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)              | 18 Nov 2020 16:15:10 |
| User entered 'No (N)' | Kaitlyn Van Leuvan<br>(b) (4) | 03 Nov 2020 17:55:02 |

US3762161

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

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 11:14:36**

[Separate Dosage Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 03 Nov 2020 17:55:02 |

US3762161

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

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 11:14:36**

[Interval Dosage Unit Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 03 Nov 2020 17:55:02 |

US3762161

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

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 11:14:36**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User   | Time (GMT)           |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 03 Nov 2020 17:55:02 |



US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:14:36

[Name of Medication](#)

| Audit                                                                                                                                                                                                                   | User                            | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------|----------------------|
| DataPoint Verified.                                                                                                                                                                                                     | (b) (4), (b) (6)                | 18 Nov 2020 16:15:10 |
| User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: BIGUANIDES, PRODUCT: METFORMIN - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4) | 03 Nov 2020 17:57:23 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.                                                                                                               | Coder Import (b) (4)<br>(b) (4) | 03 Nov 2020 17:57:23 |
| Data point term sent to Coder                                                                                                                                                                                           | System                          | 03 Nov 2020 17:56:35 |
| User entered 'metformin'                                                                                                                                                                                                | Kaitlyn Van Leuvan<br>(b) (4)   | 03 Nov 2020 17:55:52 |

US3762161

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

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 11:14:36**

[Prophylaxis](#)

| Audit                 | User                          | Time (GMT)           |
|-----------------------|-------------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)              | 18 Nov 2020 16:15:10 |
| User entered 'No (N)' | Kaitlyn Van Leuvan<br>(b) (4) | 03 Nov 2020 17:55:52 |

US3762161

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

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 11:14:36**

[Indication](#)

| Audit                           | User                          | Time (GMT)           |
|---------------------------------|-------------------------------|----------------------|
| DataPoint Verified.             | (b) (4), (b) (6)              | 18 Nov 2020 16:15:10 |
| User entered 'Type II DIABETES' | Kaitlyn Van Leuvan<br>(b) (4) | 03 Nov 2020 17:55:52 |

US3762161

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

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 11:14:36**

[Dose per administration](#)

| Audit                                                   | User                          | Time (GMT)           |
|---------------------------------------------------------|-------------------------------|----------------------|
| DataPoint Verified.                                     | (b) (4), (b) (6)              | 18 Nov 2020 16:15:10 |
| User entered '1000' reason for change: Data Entry Error | Kaitlyn Van Leuvan<br>(b) (4) | 03 Nov 2020 17:57:24 |
| User entered '100'                                      | Kaitlyn Van Leuvan<br>(b) (4) | 03 Nov 2020 17:55:52 |

US3762161

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

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 11:14:36**

[Dose unit](#)

| Audit                  | User                          | Time (GMT)           |
|------------------------|-------------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)              | 18 Nov 2020 16:15:10 |
| User entered 'mg (mg)' | Kaitlyn Van Leuvan<br>(b) (4) | 03 Nov 2020 17:55:52 |

US3762161

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

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 11:14:36**

If dose unit is Other, specify

| Audit               | User                          | Time (GMT)           |
|---------------------|-------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)              | 18 Nov 2020 16:15:10 |
| User entered empty. | Kaitlyn Van Leuvan<br>(b) (4) | 03 Nov 2020 17:55:52 |

US3762161

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

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 11:14:36**

[Frequency](#)

| Audit                          | User                          | Time (GMT)           |
|--------------------------------|-------------------------------|----------------------|
| DataPoint Verified.            | (b) (4), (b) (6)              | 18 Nov 2020 16:15:10 |
| User entered 'once daily (QD)' | Kaitlyn Van Leuvan<br>(b) (4) | 03 Nov 2020 17:55:52 |

US3762161

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

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 11:14:36**

[If frequency is Other, specify](#)

| Audit               | User                          | Time (GMT)           |
|---------------------|-------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)              | 18 Nov 2020 16:15:10 |
| User entered empty. | Kaitlyn Van Leuvan<br>(b) (4) | 03 Nov 2020 17:55:52 |



US3762161

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

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 11:14:36**

[Route of administration](#)

| Audit                      | User                          | Time (GMT)           |
|----------------------------|-------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)              | 18 Nov 2020 16:15:10 |
| User entered 'Oral (ORAL)' | Kaitlyn Van Leuvan<br>(b) (4) | 03 Nov 2020 17:55:52 |

US3762161

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

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 11:14:36**

If route of administration is Other, specify

| Audit               | User                          | Time (GMT)           |
|---------------------|-------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)              | 18 Nov 2020 16:15:10 |
| User entered empty. | Kaitlyn Van Leuvan<br>(b) (4) | 03 Nov 2020 17:55:52 |

US3762161

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

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 11:14:36**

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

| Audit                                                          | User               | Time (GMT)           |
|----------------------------------------------------------------|--------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)   | 18 Nov 2020 16:15:10 |
| User entered 'UN Feb 2007' reason for change: Data Entry Error | Kaitlyn Van Leuvan | 03 Nov 2020 17:57:24 |
| User entered 'un Feb 2017'                                     | (b) (4)            |                      |
|                                                                | Kaitlyn Van Leuvan | 03 Nov 2020 17:55:52 |
|                                                                | (b) (4)            |                      |

US3762161

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

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 11:14:36**

[Start date completely unknown](#)

| Audit               | User                          | Time (GMT)           |
|---------------------|-------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)              | 18 Nov 2020 16:15:10 |
| User entered '0'    | Kaitlyn Van Leuvan<br>(b) (4) | 03 Nov 2020 17:55:52 |

US3762161

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

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 11:14:36**

[Ongoing?](#)

| Audit                  | User                          | Time (GMT)           |
|------------------------|-------------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)              | 18 Nov 2020 16:15:10 |
| User entered 'Yes (Y)' | Kaitlyn Van Leuvan<br>(b) (4) | 03 Nov 2020 17:55:52 |

US3762161

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

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 11:14:36**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit               | User                          | Time (GMT)           |
|---------------------|-------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)              | 18 Nov 2020 16:15:10 |
| User entered empty. | Kaitlyn Van Leuvan<br>(b) (4) | 03 Nov 2020 17:55:52 |

US3762161

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

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 11:14:36**

[Was this medication taken for solicited event?](#)

| Audit                 | User                          | Time (GMT)           |
|-----------------------|-------------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)              | 18 Nov 2020 16:15:10 |
| User entered 'No (N)' | Kaitlyn Van Leuvan<br>(b) (4) | 03 Nov 2020 17:55:52 |

US3762161

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

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 11:14:36**

[Separate Dosage Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 03 Nov 2020 17:55:52 |



US3762161

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

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 11:14:36**

[Interval Dosage Unit Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 03 Nov 2020 17:55:52 |

US3762161

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

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 11:14:36**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User   | Time (GMT)           |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 03 Nov 2020 17:55:52 |

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:14:36

[Name of Medication](#)

| Audit                                                                                                                                                                                                   | User                            | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------|----------------------|
| DataPoint Verified.                                                                                                                                                                                     | (b) (4), (b) (6)                | 18 Nov 2020 16:15:10 |
| User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: GABAPENTIN - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4) | 03 Nov 2020 18:00:22 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.                                                                                               | Coder Import (b) (4)<br>(b) (4) | 03 Nov 2020 18:00:22 |
| Data point term sent to Coder                                                                                                                                                                           | System                          | 03 Nov 2020 17:59:41 |
| User entered 'Gabapentin'                                                                                                                                                                               | Kaitlyn Van Leuvan<br>(b) (4)   | 03 Nov 2020 17:59:09 |

US3762161

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

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 11:14:36**

[Prophylaxis](#)

| Audit                  | User                          | Time (GMT)           |
|------------------------|-------------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)              | 18 Nov 2020 16:15:10 |
| User entered 'Yes (Y)' | Kaitlyn Van Leuvan<br>(b) (4) | 03 Nov 2020 17:59:09 |

US3762161

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

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 11:14:36**

[Indication](#)

| Audit                     | User                          | Time (GMT)           |
|---------------------------|-------------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)              | 18 Nov 2020 16:15:10 |
| User entered 'Neuropathy' | Kaitlyn Van Leuvan<br>(b) (4) | 03 Nov 2020 17:59:09 |

US3762161

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

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 11:14:36**

[Dose per administration](#)

| Audit               | User                          | Time (GMT)           |
|---------------------|-------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)              | 18 Nov 2020 16:15:10 |
| User entered '800'  | Kaitlyn Van Leuvan<br>(b) (4) | 03 Nov 2020 17:59:09 |

US3762161

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

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 11:14:36**

[Dose unit](#)

| Audit                  | User                          | Time (GMT)           |
|------------------------|-------------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)              | 18 Nov 2020 16:15:10 |
| User entered 'mg (mg)' | Kaitlyn Van Leuvan<br>(b) (4) | 03 Nov 2020 17:59:09 |

US3762161

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

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 11:14:36**

[If dose unit is Other, specify](#)

| Audit               | User                          | Time (GMT)           |
|---------------------|-------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)              | 18 Nov 2020 16:15:10 |
| User entered empty. | Kaitlyn Van Leuvan<br>(b) (4) | 03 Nov 2020 17:59:09 |



US3762161

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

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 11:14:36**

[Frequency](#)

| Audit                                 | User                          | Time (GMT)           |
|---------------------------------------|-------------------------------|----------------------|
| DataPoint Verified.                   | (b) (4), (b) (6)              | 18 Nov 2020 16:15:10 |
| User entered 'four times daily (QID)' | Kaitlyn Van Leuvan<br>(b) (4) | 03 Nov 2020 17:59:09 |

US3762161

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 11:14:36**

[If frequency is Other, specify](#)

| Audit               | User                          | Time (GMT)           |
|---------------------|-------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)              | 18 Nov 2020 16:15:10 |
| User entered empty. | Kaitlyn Van Leuvan<br>(b) (4) | 03 Nov 2020 17:59:09 |

US3762161

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 11:14:36**

[Route of administration](#)

| Audit                      | User                          | Time (GMT)           |
|----------------------------|-------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)              | 18 Nov 2020 16:15:10 |
| User entered 'Oral (ORAL)' | Kaitlyn Van Leuvan<br>(b) (4) | 03 Nov 2020 17:59:09 |

US3762161

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 11:14:36**

If route of administration is Other, specify

| Audit               | User                          | Time (GMT)           |
|---------------------|-------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)              | 18 Nov 2020 16:15:10 |
| User entered empty. | Kaitlyn Van Leuvan<br>(b) (4) | 03 Nov 2020 17:59:09 |

US3762161

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 11:14:36**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                          | Time (GMT)           |
|----------------------------|-------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)              | 18 Nov 2020 16:15:10 |
| User entered 'un UNK 2010' | Kaitlyn Van Leuvan<br>(b) (4) | 03 Nov 2020 17:59:09 |

US3762161

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 11:14:36**

[Start date completely unknown](#)

| Audit               | User                          | Time (GMT)           |
|---------------------|-------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)              | 18 Nov 2020 16:15:10 |
| User entered '0'    | Kaitlyn Van Leuvan<br>(b) (4) | 03 Nov 2020 17:59:09 |

US3762161

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 11:14:36**

[Ongoing?](#)

| Audit                  | User                          | Time (GMT)           |
|------------------------|-------------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)              | 18 Nov 2020 16:15:10 |
| User entered 'Yes (Y)' | Kaitlyn Van Leuvan<br>(b) (4) | 03 Nov 2020 17:59:09 |

US3762161

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 11:14:36**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit               | User                          | Time (GMT)           |
|---------------------|-------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)              | 18 Nov 2020 16:15:10 |
| User entered empty. | Kaitlyn Van Leuvan<br>(b) (4) | 03 Nov 2020 17:59:09 |



US3762161

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 11:14:36**

[Was this medication taken for solicited event?](#)

| Audit                 | User                          | Time (GMT)           |
|-----------------------|-------------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)              | 18 Nov 2020 16:15:10 |
| User entered 'No (N)' | Kaitlyn Van Leuvan<br>(b) (4) | 03 Nov 2020 17:59:09 |

US3762161

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 11:14:36**

[Separate Dosage Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '4' | System | 03 Nov 2020 17:59:09 |

US3762161

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 11:14:36**

[Interval Dosage Unit Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 03 Nov 2020 17:59:09 |

US3762161

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 11:14:36**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User   | Time (GMT)           |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 03 Nov 2020 17:59:09 |

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:14:36

[Name of Medication](#)

| Audit                                                                                                                                                                                                                                                                                        | User                            | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------|----------------------|
| DataPoint Verified.                                                                                                                                                                                                                                                                          | (b) (4), (b) (6)                | 18 Nov 2020 16:15:10 |
| User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4) | 03 Nov 2020 18:01:23 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.                                                                                                                                                                                    | Coder Import (b) (4)<br>(b) (4) | 03 Nov 2020 18:01:23 |
| Data point term sent to Coder                                                                                                                                                                                                                                                                | System                          | 03 Nov 2020 18:00:41 |
| User entered 'Aspirin'                                                                                                                                                                                                                                                                       | Kaitlyn Van Leuvan<br>(b) (4)   | 03 Nov 2020 18:00:19 |

US3762161

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 11:14:36**

[Prophylaxis](#)

| Audit                  | User                          | Time (GMT)           |
|------------------------|-------------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)              | 18 Nov 2020 16:15:10 |
| User entered 'Yes (Y)' | Kaitlyn Van Leuvan<br>(b) (4) | 03 Nov 2020 18:00:19 |

US3762161

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 11:14:36**

[Indication](#)

| Audit                       | User                          | Time (GMT)           |
|-----------------------------|-------------------------------|----------------------|
| DataPoint Verified.         | (b) (4), (b) (6)              | 18 Nov 2020 16:15:10 |
| User entered 'Heart health' | Kaitlyn Van Leuvan<br>(b) (4) | 03 Nov 2020 18:00:19 |

US3762161

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 11:14:36**

[Dose per administration](#)

| Audit               | User                          | Time (GMT)           |
|---------------------|-------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)              | 18 Nov 2020 16:15:10 |
| User entered '325'  | Kaitlyn Van Leuvan<br>(b) (4) | 03 Nov 2020 18:00:19 |



US3762161

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 11:14:36**

[Dose unit](#)

| Audit                  | User                          | Time (GMT)           |
|------------------------|-------------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)              | 18 Nov 2020 16:15:10 |
| User entered 'mg (mg)' | Kaitlyn Van Leuvan<br>(b) (4) | 03 Nov 2020 18:00:19 |

US3762161

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 11:14:36**

If dose unit is Other, specify

| Audit               | User                          | Time (GMT)           |
|---------------------|-------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)              | 18 Nov 2020 16:15:10 |
| User entered empty. | Kaitlyn Van Leuvan<br>(b) (4) | 03 Nov 2020 18:00:19 |

US3762161

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 11:14:36**

[Frequency](#)

| Audit                          | User                          | Time (GMT)           |
|--------------------------------|-------------------------------|----------------------|
| DataPoint Verified.            | (b) (4), (b) (6)              | 18 Nov 2020 16:15:10 |
| User entered 'once daily (QD)' | Kaitlyn Van Leuvan<br>(b) (4) | 03 Nov 2020 18:00:19 |

US3762161

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 11:14:36**

[If frequency is Other, specify](#)

| Audit               | User                          | Time (GMT)           |
|---------------------|-------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)              | 18 Nov 2020 16:15:10 |
| User entered empty. | Kaitlyn Van Leuvan<br>(b) (4) | 03 Nov 2020 18:00:19 |

US3762161

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 11:14:36**

[Route of administration](#)

| Audit                      | User                          | Time (GMT)           |
|----------------------------|-------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)              | 18 Nov 2020 16:15:10 |
| User entered 'Oral (ORAL)' | Kaitlyn Van Leuvan<br>(b) (4) | 03 Nov 2020 18:00:19 |

US3762161

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 11:14:36**

If route of administration is Other, specify

| Audit               | User                          | Time (GMT)           |
|---------------------|-------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)              | 18 Nov 2020 16:15:10 |
| User entered empty. | Kaitlyn Van Leuvan<br>(b) (4) | 03 Nov 2020 18:00:19 |

US3762161

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 11:14:36**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                          | Time (GMT)           |
|----------------------------|-------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)              | 18 Nov 2020 16:15:10 |
| User entered 'un UNK 2005' | Kaitlyn Van Leuvan<br>(b) (4) | 03 Nov 2020 18:00:19 |

US3762161

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 11:14:36**

[Start date completely unknown](#)

| Audit               | User                          | Time (GMT)           |
|---------------------|-------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)              | 18 Nov 2020 16:15:10 |
| User entered '0'    | Kaitlyn Van Leuvan<br>(b) (4) | 03 Nov 2020 18:00:19 |



US3762161

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 11:14:36**

[Ongoing?](#)

| Audit                  | User                          | Time (GMT)           |
|------------------------|-------------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)              | 18 Nov 2020 16:15:10 |
| User entered 'Yes (Y)' | Kaitlyn Van Leuvan<br>(b) (4) | 03 Nov 2020 18:00:19 |

US3762161

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 11:14:36**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit               | User                          | Time (GMT)           |
|---------------------|-------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)              | 18 Nov 2020 16:15:10 |
| User entered empty. | Kaitlyn Van Leuvan<br>(b) (4) | 03 Nov 2020 18:00:19 |

US3762161

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 11:14:36**

[Was this medication taken for solicited event?](#)

| Audit                 | User                          | Time (GMT)           |
|-----------------------|-------------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)              | 18 Nov 2020 16:15:10 |
| User entered 'No (N)' | Kaitlyn Van Leuvan<br>(b) (4) | 03 Nov 2020 18:00:19 |

US3762161

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 11:14:36**

[Separate Dosage Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 03 Nov 2020 18:00:19 |

US3762161

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 11:14:36**

[Interval Dosage Unit Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 03 Nov 2020 18:00:19 |

US3762161

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 11:14:36**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User   | Time (GMT)           |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 03 Nov 2020 18:00:19 |

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:14:36

[Name of Medication](#)

| Audit                                                                                                                                                                                                                                                                  | User                            | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------|----------------------|
| DataPoint Verified.                                                                                                                                                                                                                                                    | (b) (4), (b) (6)                | 18 Nov 2020 16:15:10 |
| User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, FAST-ACTING, PRODUCT: INSULIN LISPRO, PRODUCTSYNONYM: HUMALOG - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4) | 03 Nov 2020 18:03:27 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.                                                                                                                                                              | Coder Import (b) (4)<br>(b) (4) | 03 Nov 2020 18:03:27 |
| Data point term sent to Coder                                                                                                                                                                                                                                          | System                          | 03 Nov 2020 18:02:47 |
| User entered 'Humalog'                                                                                                                                                                                                                                                 | Kaitlyn Van Leuvan<br>(b) (4)   | 03 Nov 2020 18:02:23 |

US3762161

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 11:14:36**

[Prophylaxis](#)

| Audit                  | User                          | Time (GMT)           |
|------------------------|-------------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)              | 18 Nov 2020 16:15:10 |
| User entered 'Yes (Y)' | Kaitlyn Van Leuvan<br>(b) (4) | 03 Nov 2020 18:02:23 |



US3762161

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 11:14:36**

[Indication](#)

| Audit                           | User                          | Time (GMT)           |
|---------------------------------|-------------------------------|----------------------|
| DataPoint Verified.             | (b) (4), (b) (6)              | 18 Nov 2020 16:15:10 |
| User entered 'Type II Diabetes' | Kaitlyn Van Leuvan<br>(b) (4) | 03 Nov 2020 18:02:23 |

US3762161

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 11:14:36**

[Dose per administration](#)

| Audit               | User                          | Time (GMT)           |
|---------------------|-------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)              | 18 Nov 2020 16:15:10 |
| User entered '100'  | Kaitlyn Van Leuvan<br>(b) (4) | 03 Nov 2020 18:02:23 |

US3762161

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 11:14:36**

[Dose unit](#)

| Audit                  | User                          | Time (GMT)           |
|------------------------|-------------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)              | 18 Nov 2020 16:15:10 |
| User entered 'IU (IU)' | Kaitlyn Van Leuvan<br>(b) (4) | 03 Nov 2020 18:02:23 |

US3762161

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 11:14:36**

If dose unit is Other, specify

| Audit               | User                          | Time (GMT)           |
|---------------------|-------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)              | 18 Nov 2020 16:15:10 |
| User entered empty. | Kaitlyn Van Leuvan<br>(b) (4) | 03 Nov 2020 18:02:23 |

US3762161

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 11:14:36**

[Frequency](#)

| Audit                                 | User                          | Time (GMT)           |
|---------------------------------------|-------------------------------|----------------------|
| DataPoint Verified.                   | (b) (4), (b) (6)              | 18 Nov 2020 16:15:10 |
| User entered 'four times daily (QID)' | Kaitlyn Van Leuvan<br>(b) (4) | 03 Nov 2020 18:02:23 |

US3762161

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 11:14:36**

[If frequency is Other, specify](#)

| Audit               | User                          | Time (GMT)           |
|---------------------|-------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)              | 18 Nov 2020 16:15:10 |
| User entered empty. | Kaitlyn Van Leuvan<br>(b) (4) | 03 Nov 2020 18:02:23 |

US3762161

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 11:14:36**

[Route of administration](#)

| Audit                                      | User                          | Time (GMT)           |
|--------------------------------------------|-------------------------------|----------------------|
| DataPoint Verified.                        | (b) (4), (b) (6)              | 18 Nov 2020 16:15:10 |
| User entered 'Subcutaneous (SUBCUTANEOUS)' | Kaitlyn Van Leuvan<br>(b) (4) | 03 Nov 2020 18:02:23 |

US3762161

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 11:14:36**

If route of administration is Other, specify

| Audit               | User                          | Time (GMT)           |
|---------------------|-------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)              | 18 Nov 2020 16:15:10 |
| User entered empty. | Kaitlyn Van Leuvan<br>(b) (4) | 03 Nov 2020 18:02:23 |



US3762161

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 11:14:36**

[Start date \(dd MMM yyyy\)](#)

| Audit                                                                                   | User                          | Time (GMT)           |
|-----------------------------------------------------------------------------------------|-------------------------------|----------------------|
| DataPoint Verified.                                                                     | (b) (4), (b) (6)              | 18 Nov 2020 16:15:10 |
| User closed query 'Data entered is non-conformant. Please correct.' (Site from System). | System                        | 03 Nov 2020 18:02:51 |
| User entered 'Un UNK 1998' reason for change: Data Entry Error                          | Kaitlyn Van Leuvan<br>(b) (4) | 03 Nov 2020 18:02:51 |
| User opened query 'Data entered is non-conformant. Please correct.' (Site from System). | System                        | 03 Nov 2020 18:02:23 |
| User entered 'uu UNK 1998' (non-conformant).                                            | Kaitlyn Van Leuvan<br>(b) (4) | 03 Nov 2020 18:02:23 |

US3762161

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 11:14:36**

[Start date completely unknown](#)

| Audit               | User                          | Time (GMT)           |
|---------------------|-------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)              | 18 Nov 2020 16:15:10 |
| User entered '0'    | Kaitlyn Van Leuvan<br>(b) (4) | 03 Nov 2020 18:02:23 |

US3762161

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 11:14:36**

[Ongoing?](#)

| Audit                  | User                          | Time (GMT)           |
|------------------------|-------------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)              | 18 Nov 2020 16:15:10 |
| User entered 'Yes (Y)' | Kaitlyn Van Leuvan<br>(b) (4) | 03 Nov 2020 18:02:23 |

US3762161

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 11:14:36**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit               | User                          | Time (GMT)           |
|---------------------|-------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)              | 18 Nov 2020 16:15:10 |
| User entered empty. | Kaitlyn Van Leuvan<br>(b) (4) | 03 Nov 2020 18:02:23 |

US3762161

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 11:14:36**

[Was this medication taken for solicited event?](#)

| Audit                 | User                          | Time (GMT)           |
|-----------------------|-------------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)              | 18 Nov 2020 16:15:10 |
| User entered 'No (N)' | Kaitlyn Van Leuvan<br>(b) (4) | 03 Nov 2020 18:02:23 |

US3762161

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 11:14:36**

[Separate Dosage Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '4' | System | 03 Nov 2020 18:02:23 |

US3762161

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 11:14:36**

[Interval Dosage Unit Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 03 Nov 2020 18:02:23 |

US3762161

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 11:14:36**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User   | Time (GMT)           |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 03 Nov 2020 18:02:23 |



US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:14:36

[Name of Medication](#)

| Audit                                                                                                                                                                                                                                                                   | User                            | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------|----------------------|
| DataPoint Verified.                                                                                                                                                                                                                                                     | (b) (4), (b) (6)                | 18 Nov 2020 16:15:10 |
| User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, LONG-ACTING, PRODUCT: INSULIN DETEMIR, PRODUCTSYNONYM: LEVEMIR - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4) | 03 Nov 2020 18:06:23 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.                                                                                                                                                               | Coder Import (b) (4)<br>(b) (4) | 03 Nov 2020 18:06:23 |
| Data point term sent to Coder                                                                                                                                                                                                                                           | System                          | 03 Nov 2020 18:05:49 |
| User entered 'Levemir'                                                                                                                                                                                                                                                  | Kaitlyn Van Leuvan<br>(b) (4)   | 03 Nov 2020 18:05:19 |

US3762161

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 11:14:36**

[Prophylaxis](#)

| Audit                 | User                          | Time (GMT)           |
|-----------------------|-------------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)              | 18 Nov 2020 16:15:10 |
| User entered 'No (N)' | Kaitlyn Van Leuvan<br>(b) (4) | 03 Nov 2020 18:05:19 |

US3762161

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 11:14:36**

[Indication](#)

| Audit                           | User                          | Time (GMT)           |
|---------------------------------|-------------------------------|----------------------|
| DataPoint Verified.             | (b) (4), (b) (6)              | 18 Nov 2020 16:15:10 |
| User entered 'Type II Diabetes' | Kaitlyn Van Leuvan<br>(b) (4) | 03 Nov 2020 18:05:19 |

US3762161

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 11:14:36**

[Dose per administration](#)

| Audit               | User                          | Time (GMT)           |
|---------------------|-------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)              | 18 Nov 2020 16:15:10 |
| User entered '56'   | Kaitlyn Van Leuvan<br>(b) (4) | 03 Nov 2020 18:05:19 |

US3762161

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 11:14:36**

[Dose unit](#)

| Audit                  | User                          | Time (GMT)           |
|------------------------|-------------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)              | 18 Nov 2020 16:15:10 |
| User entered 'IU (IU)' | Kaitlyn Van Leuvan<br>(b) (4) | 03 Nov 2020 18:05:19 |

US3762161

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 11:14:36**

If dose unit is Other, specify

| Audit               | User                          | Time (GMT)           |
|---------------------|-------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)              | 18 Nov 2020 16:15:10 |
| User entered empty. | Kaitlyn Van Leuvan<br>(b) (4) | 03 Nov 2020 18:05:19 |

US3762161

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 11:14:36**

[Frequency](#)

| Audit                          | User                          | Time (GMT)           |
|--------------------------------|-------------------------------|----------------------|
| DataPoint Verified.            | (b) (4), (b) (6)              | 18 Nov 2020 16:15:10 |
| User entered 'once daily (QD)' | Kaitlyn Van Leuvan<br>(b) (4) | 03 Nov 2020 18:05:19 |

US3762161

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 11:14:36**

[If frequency is Other, specify](#)

| Audit               | User                          | Time (GMT)           |
|---------------------|-------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)              | 18 Nov 2020 16:15:10 |
| User entered empty. | Kaitlyn Van Leuvan<br>(b) (4) | 03 Nov 2020 18:05:19 |



US3762161

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 11:14:36**

[Route of administration](#)

| Audit                                      | User                          | Time (GMT)           |
|--------------------------------------------|-------------------------------|----------------------|
| DataPoint Verified.                        | (b) (4), (b) (6)              | 18 Nov 2020 16:15:10 |
| User entered 'Subcutaneous (SUBCUTANEOUS)' | Kaitlyn Van Leuvan<br>(b) (4) | 03 Nov 2020 18:05:19 |

US3762161

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 11:14:36**

If route of administration is Other, specify

| Audit               | User                          | Time (GMT)           |
|---------------------|-------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)              | 18 Nov 2020 16:15:10 |
| User entered empty. | Kaitlyn Van Leuvan<br>(b) (4) | 03 Nov 2020 18:05:19 |

US3762161

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 11:14:36**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                          | Time (GMT)           |
|----------------------------|-------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)              | 18 Nov 2020 16:15:10 |
| User entered 'un UNK 2007' | Kaitlyn Van Leuvan<br>(b) (4) | 03 Nov 2020 18:05:19 |

US3762161

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 11:14:36**

[Start date completely unknown](#)

| Audit               | User                          | Time (GMT)           |
|---------------------|-------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)              | 18 Nov 2020 16:15:10 |
| User entered '0'    | Kaitlyn Van Leuvan<br>(b) (4) | 03 Nov 2020 18:05:19 |

US3762161

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 11:14:36**

[Ongoing?](#)

| Audit                  | User                          | Time (GMT)           |
|------------------------|-------------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)              | 18 Nov 2020 16:15:10 |
| User entered 'Yes (Y)' | Kaitlyn Van Leuvan<br>(b) (4) | 03 Nov 2020 18:05:19 |

US3762161

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 11:14:36**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit               | User                          | Time (GMT)           |
|---------------------|-------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)              | 18 Nov 2020 16:15:10 |
| User entered empty. | Kaitlyn Van Leuvan<br>(b) (4) | 03 Nov 2020 18:05:19 |

US3762161

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 11:14:36**

[Was this medication taken for solicited event?](#)

| Audit                 | User                          | Time (GMT)           |
|-----------------------|-------------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)              | 18 Nov 2020 16:15:10 |
| User entered 'No (N)' | Kaitlyn Van Leuvan<br>(b) (4) | 03 Nov 2020 18:05:19 |

US3762161

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 11:14:36**

[Separate Dosage Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 03 Nov 2020 18:05:19 |



US3762161

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 11:14:36**

[Interval Dosage Unit Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 03 Nov 2020 18:05:19 |

US3762161

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 11:14:36**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User   | Time (GMT)           |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 03 Nov 2020 18:05:19 |

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:14:36

Name of Medication

| Audit                                                                                                                                                                                                                                                                                                 | User                                | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|----------------------|
| User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: THIRD-GENERATION CEPHALOSPORINS, PRODUCT: CEFDINIR, PRODUCTSYNONYM: OMNICEF [CEFDINIR] - version WHODrug-Global-B3\202003.                           | Coder Import (b) (4)<br>(b) (4)     | 25 Nov 2020 03:21:05 |
| 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)     | 25 Nov 2020 03:21:05 |
| Data point term sent to Coder                                                                                                                                                                                                                                                                         | System                              | 24 Nov 2020 19:55:49 |
| User closed query 'CDM Coding: This medication can be referred as multiple ingredients in the standard coding dictionary. Please enter all the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. Thank you.' (Site from System).              | System                              | 24 Nov 2020 19:55:25 |
| Query 'CDM Coding: This medication can be referred as multiple ingredients in the standard coding dictionary. Please enter all the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. Thank you.' answered with 'iupdated' (Site from System). | Samantha Wheeler (b) (4)<br>(b) (4) | 24 Nov 2020 19:55:25 |
| DataPoint Un-verified.                                                                                                                                                                                                                                                                                | Samantha Wheeler (b) (4)<br>(b) (4) | 24 Nov 2020 19:55:08 |
| User entered 'OMNICEF [cefdinir]' reason for change: Data Entry Error                                                                                                                                                                                                                                 | Samantha Wheeler (b) (4)<br>(b) (4) | 24 Nov 2020 19:55:08 |
| User opened query 'CDM Coding: This medication can be referred as multiple ingredients in the standard coding dictionary. Please enter all the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. Thank you.' (Site from System).              | Coder Import (b) (4)<br>(b) (4)     | 23 Nov 2020 13:26:50 |
| DataPoint Verified.                                                                                                                                                                                                                                                                                   | (b) (4), (b) (6)<br>(b) (4)         | 18 Nov 2020 16:15:10 |
| Data point term sent to Coder                                                                                                                                                                                                                                                                         | System                              | 18 Nov 2020 14:37:13 |
| User entered 'omnicef'                                                                                                                                                                                                                                                                                | Samantha Wheeler (b) (4)<br>(b) (4) | 18 Nov 2020 14:36:44 |

US3762161

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 11:14:36**

[Prophylaxis](#)

| Audit                 | User                     | Time (GMT)           |
|-----------------------|--------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)         | 18 Nov 2020 16:15:10 |
| User entered 'No (N)' | Samantha Wheeler (b) (4) | 18 Nov 2020 14:36:44 |
|                       | (b) (4)                  |                      |

US3762161

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 11:14:36**

[Indication](#)

| Audit                    | User                     | Time (GMT)           |
|--------------------------|--------------------------|----------------------|
| DataPoint Verified.      | (b) (4), (b) (6)         | 18 Nov 2020 16:15:10 |
| User entered 'pneumonia' | Samantha Wheeler (b) (4) | 18 Nov 2020 14:36:44 |
|                          | (b) (4)                  |                      |

US3762161

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 11:14:36**

[Dose per administration](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 18 Nov 2020 16:15:10 |
| User entered '300'  | Samantha Wheeler (b) (4) | 18 Nov 2020 14:36:44 |
|                     | (b) (4)                  |                      |

US3762161

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 11:14:36**

[Dose unit](#)

| Audit                  | User                     | Time (GMT)           |
|------------------------|--------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)         | 18 Nov 2020 16:15:10 |
| User entered 'mg (mg)' | Samantha Wheeler (b) (4) | 18 Nov 2020 14:36:44 |
|                        | (b) (4)                  |                      |

US3762161

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 11:14:36**

[If dose unit is Other, specify](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 18 Nov 2020 16:15:10 |
| User entered empty. | Samantha Wheeler (b) (4) | 18 Nov 2020 14:36:44 |
|                     | (b) (4)                  |                      |



US3762161

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 11:14:36**

[Frequency](#)

| Audit                            | User                     | Time (GMT)           |
|----------------------------------|--------------------------|----------------------|
| DataPoint Verified.              | (b) (4), (b) (6)         | 18 Nov 2020 16:15:10 |
| User entered 'twice daily (BID)' | Samantha Wheeler (b) (4) | 18 Nov 2020 14:36:44 |
|                                  | (b) (4)                  |                      |

US3762161

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 11:14:36**

[If frequency is Other, specify](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 18 Nov 2020 16:15:10 |
| User entered empty. | Samantha Wheeler (b) (4) | 18 Nov 2020 14:36:44 |
|                     | (b) (4)                  |                      |

US3762161

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 11:14:36**

[Route of administration](#)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)         | 18 Nov 2020 16:15:10 |
| User entered 'Oral (ORAL)' | Samantha Wheeler (b) (4) | 18 Nov 2020 14:36:44 |
|                            | (b) (4)                  |                      |

US3762161

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 11:14:36**

If route of administration is Other, specify

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 18 Nov 2020 16:15:10 |
| User entered empty. | Samantha Wheeler (b) (4) | 18 Nov 2020 14:36:44 |
|                     | (b) (4)                  |                      |

US3762161

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 11:14:36**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)         | 18 Nov 2020 16:15:10 |
| User entered '15 Nov 2020' | Samantha Wheeler (b) (4) | 18 Nov 2020 14:36:44 |
|                            | (b) (4)                  |                      |

US3762161

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 11:14:36**

[Start date completely unknown](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 18 Nov 2020 16:15:10 |
| User entered '0'    | Samantha Wheeler (b) (4) | 18 Nov 2020 14:36:44 |
|                     | (b) (4)                  |                      |

US3762161

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 11:14:36**

[Ongoing?](#)

| Audit                  | User                     | Time (GMT)           |
|------------------------|--------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)         | 18 Nov 2020 16:15:10 |
| User entered 'Yes (Y)' | Samantha Wheeler (b) (4) | 18 Nov 2020 14:36:44 |
|                        | (b) (4)                  |                      |

US3762161

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 11:14:36**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 18 Nov 2020 16:15:10 |
| User entered empty. | Samantha Wheeler (b) (4) | 18 Nov 2020 14:36:44 |
|                     | (b) (4)                  |                      |



US3762161

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 11:14:36**

[Was this medication taken for solicited event?](#)

| Audit                 | User                     | Time (GMT)           |
|-----------------------|--------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)         | 18 Nov 2020 16:15:10 |
| User entered 'No (N)' | Samantha Wheeler (b) (4) | 18 Nov 2020 14:36:44 |
|                       | (b) (4)                  |                      |

US3762161

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 11:14:36**

[Separate Dosage Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '2' | System | 18 Nov 2020 14:36:44 |

US3762161

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 11:14:36**

[Interval Dosage Unit Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 18 Nov 2020 14:36:44 |

US3762161

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 11:14:36**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User   | Time (GMT)           |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 18 Nov 2020 14:36:44 |

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:14:36

[Name of Medication](#)

| Audit                                                                                                                                                                                                          | User                                | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|----------------------|
| User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: TETRACYCLINES, ATC: TETRACYCLINES, PRODUCT: DOXYCYCLINE HYCLATE - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4)     | 19 Nov 2020 12:03:07 |
| User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.                                                                                                             | Coder Import (b) (4)<br>(b) (4)     | 19 Nov 2020 12:03:07 |
| DataPoint Verified.                                                                                                                                                                                            | (b) (4), (b) (6)                    | 18 Nov 2020 16:15:10 |
| Data point term sent to Coder                                                                                                                                                                                  | System                              | 18 Nov 2020 14:49:22 |
| User entered 'doxycycline hyclate'                                                                                                                                                                             | Samantha Wheeler (b) (4)<br>(b) (4) | 18 Nov 2020 14:48:55 |

US3762161

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 11:14:36**

[Prophylaxis](#)

| Audit                 | User                     | Time (GMT)           |
|-----------------------|--------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)         | 18 Nov 2020 16:15:10 |
| User entered 'No (N)' | Samantha Wheeler (b) (4) | 18 Nov 2020 14:48:55 |
|                       | (b) (4)                  |                      |

US3762161

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 11:14:36**

[Indication](#)

| Audit                    | User                     | Time (GMT)           |
|--------------------------|--------------------------|----------------------|
| DataPoint Verified.      | (b) (4), (b) (6)         | 18 Nov 2020 16:15:10 |
| User entered 'pneumonia' | Samantha Wheeler (b) (4) | 18 Nov 2020 14:48:55 |
|                          | (b) (4)                  |                      |

US3762161

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 11:14:36**

[Dose per administration](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 18 Nov 2020 16:15:10 |
| User entered '100'  | Samantha Wheeler (b) (4) | 18 Nov 2020 14:48:55 |
|                     | (b) (4)                  |                      |



US3762161

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 11:14:36**

[Dose unit](#)

| Audit                  | User                     | Time (GMT)           |
|------------------------|--------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)         | 18 Nov 2020 16:15:10 |
| User entered 'mg (mg)' | Samantha Wheeler (b) (4) | 18 Nov 2020 14:48:55 |
|                        | (b) (4)                  |                      |

US3762161

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 11:14:36**

[If dose unit is Other, specify](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 18 Nov 2020 16:15:10 |
| User entered empty. | Samantha Wheeler (b) (4) | 18 Nov 2020 14:48:55 |
|                     | (b) (4)                  |                      |

US3762161

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 11:14:36**

[Frequency](#)

| Audit                            | User                     | Time (GMT)           |
|----------------------------------|--------------------------|----------------------|
| DataPoint Verified.              | (b) (4), (b) (6)         | 18 Nov 2020 16:15:10 |
| User entered 'twice daily (BID)' | Samantha Wheeler (b) (4) | 18 Nov 2020 14:48:55 |
|                                  | (b) (4)                  |                      |

US3762161

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 11:14:36**

[If frequency is Other, specify](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 18 Nov 2020 16:15:10 |
| User entered empty. | Samantha Wheeler (b) (4) | 18 Nov 2020 14:48:55 |
|                     | (b) (4)                  |                      |

US3762161

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 11:14:36**

[Route of administration](#)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)         | 18 Nov 2020 16:15:10 |
| User entered 'Oral (ORAL)' | Samantha Wheeler (b) (4) | 18 Nov 2020 14:48:55 |
|                            | (b) (4)                  |                      |

US3762161

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 11:14:36**

If route of administration is Other, specify

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 18 Nov 2020 16:15:10 |
| User entered empty. | Samantha Wheeler (b) (4) | 18 Nov 2020 14:48:55 |
|                     | (b) (4)                  |                      |

US3762161

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 11:14:36**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)         | 18 Nov 2020 16:15:10 |
| User entered '15 Nov 2020' | Samantha Wheeler (b) (4) | 18 Nov 2020 14:48:55 |
|                            | (b) (4)                  |                      |

US3762161

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 11:14:36**

[Start date completely unknown](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 18 Nov 2020 16:15:10 |
| User entered '0'    | Samantha Wheeler (b) (4) | 18 Nov 2020 14:48:55 |
|                     | (b) (4)                  |                      |



US3762161

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 11:14:36**

[Ongoing?](#)

| Audit                  | User                     | Time (GMT)           |
|------------------------|--------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)         | 18 Nov 2020 16:15:10 |
| User entered 'Yes (Y)' | Samantha Wheeler (b) (4) | 18 Nov 2020 14:48:55 |
|                        | (b) (4)                  |                      |

US3762161

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 11:14:36**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 18 Nov 2020 16:15:10 |
| User entered empty. | Samantha Wheeler (b) (4) | 18 Nov 2020 14:48:55 |
|                     | (b) (4)                  |                      |

US3762161

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 11:14:36**

[Was this medication taken for solicited event?](#)

| Audit                 | User                     | Time (GMT)           |
|-----------------------|--------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)         | 18 Nov 2020 16:15:10 |
| User entered 'No (N)' | Samantha Wheeler (b) (4) | 18 Nov 2020 14:48:55 |
|                       | (b) (4)                  |                      |

US3762161

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 11:14:36**

[Separate Dosage Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '2' | System | 18 Nov 2020 14:48:55 |

US3762161

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 11:14:36**

[Interval Dosage Unit Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 18 Nov 2020 14:48:55 |

US3762161

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 11:14:36**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User   | Time (GMT)           |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 18 Nov 2020 14:48:55 |

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:14:36

[Name of Medication](#)

| Audit                                                                                                                                                                                                                                 | User                                | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|----------------------|
| DataPoint Verified.                                                                                                                                                                                                                   | (b) (4), (b) (6)                    | 19 Nov 2020 18:06:12 |
| User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTION ADDITIVES, ATC: ELECTROLYTE SOLUTIONS, PRODUCT: SODIUM CHLORIDE - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4)     | 19 Nov 2020 03:39:57 |
| User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.                                                                                                                                    | Coder Import (b) (4)<br>(b) (4)     | 19 Nov 2020 03:39:57 |
| Data point term sent to Coder                                                                                                                                                                                                         | System                              | 18 Nov 2020 19:50:49 |
| User entered 'sodium chloride'                                                                                                                                                                                                        | Samantha Wheeler (b) (4)<br>(b) (4) | 18 Nov 2020 19:49:54 |

US3762161

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 11:14:36**

[Prophylaxis](#)

| Audit                 | User                     | Time (GMT)           |
|-----------------------|--------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)         | 19 Nov 2020 18:06:12 |
| User entered 'No (N)' | Samantha Wheeler (b) (4) | 18 Nov 2020 19:49:54 |
|                       | (b) (4)                  |                      |



US3762161

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 11:14:36**

[Indication](#)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)         | 19 Nov 2020 18:06:12 |
| User entered 'dehydration' | Samantha Wheeler (b) (4) | 18 Nov 2020 19:49:54 |
|                            | (b) (4)                  |                      |

US3762161

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 11:14:36**

[Dose per administration](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 19 Nov 2020 18:06:12 |
| User entered '100'  | Samantha Wheeler (b) (4) | 18 Nov 2020 19:49:54 |
|                     | (b) (4)                  |                      |

US3762161

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 11:14:36**

[Dose unit](#)

| Audit                        | User                     | Time (GMT)           |
|------------------------------|--------------------------|----------------------|
| DataPoint Verified.          | (b) (4), (b) (6)         | 19 Nov 2020 18:06:12 |
| User entered 'Other (OTHER)' | Samantha Wheeler (b) (4) | 18 Nov 2020 19:49:54 |
|                              | (b) (4)                  |                      |

US3762161

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 11:14:36**

If dose unit is Other, specify

| Audit                | User                     | Time (GMT)           |
|----------------------|--------------------------|----------------------|
| DataPoint Verified.  | (b) (4), (b) (6)         | 19 Nov 2020 18:06:12 |
| User entered 'mL/hr' | Samantha Wheeler (b) (4) | 18 Nov 2020 19:49:54 |
|                      | (b) (4)                  |                      |

US3762161

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 11:14:36**

[Frequency](#)

| Audit                        | User                     | Time (GMT)           |
|------------------------------|--------------------------|----------------------|
| DataPoint Verified.          | (b) (4), (b) (6)         | 19 Nov 2020 18:06:12 |
| User entered 'other (OTHER)' | Samantha Wheeler (b) (4) | 18 Nov 2020 19:49:54 |
|                              | (b) (4)                  |                      |

US3762161

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 11:14:36**

[If frequency is Other, specify](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)         | 19 Nov 2020 18:06:12 |
| User entered 'continuous' | Samantha Wheeler (b) (4) | 18 Nov 2020 19:49:54 |
|                           | (b) (4)                  |                      |

US3762161

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 11:14:36**

[Route of administration](#)

| Audit                                    | User                     | Time (GMT)           |
|------------------------------------------|--------------------------|----------------------|
| DataPoint Verified.                      | (b) (4), (b) (6)         | 19 Nov 2020 18:06:12 |
| User entered 'Intravenous (INTRAVENOUS)' | Samantha Wheeler (b) (4) | 18 Nov 2020 19:49:54 |
|                                          | (b) (4)                  |                      |

US3762161

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 11:14:36**

If route of administration is Other, specify

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 19 Nov 2020 18:06:12 |
| User entered empty. | Samantha Wheeler (b) (4) | 18 Nov 2020 19:49:54 |
|                     | (b) (4)                  |                      |



US3762161

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 11:14:36**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)         | 19 Nov 2020 18:06:12 |
| User entered '10 Nov 2020' | Samantha Wheeler (b) (4) | 18 Nov 2020 19:49:54 |
|                            | (b) (4)                  |                      |

US3762161

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 11:14:36**

[Start date completely unknown](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 19 Nov 2020 18:06:12 |
| User entered '0'    | Samantha Wheeler (b) (4) | 18 Nov 2020 19:49:54 |
|                     | (b) (4)                  |                      |

US3762161

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 11:14:36**

[Ongoing?](#)

| Audit                 | User                     | Time (GMT)           |
|-----------------------|--------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)         | 19 Nov 2020 18:06:12 |
| User entered 'No (N)' | Samantha Wheeler (b) (4) | 18 Nov 2020 19:49:54 |
|                       | (b) (4)                  |                      |

US3762161

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 11:14:36**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)         | 19 Nov 2020 18:06:12 |
| User entered '11 Nov 2020' | Samantha Wheeler (b) (4) | 18 Nov 2020 19:49:54 |
|                            | (b) (4)                  |                      |

US3762161

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 11:14:36**

[Was this medication taken for solicited event?](#)

| Audit                 | User                     | Time (GMT)           |
|-----------------------|--------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)         | 19 Nov 2020 18:06:12 |
| User entered 'No (N)' | Samantha Wheeler (b) (4) | 18 Nov 2020 19:49:54 |
|                       | (b) (4)                  |                      |

US3762161

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 11:14:36**

[Separate Dosage Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 18 Nov 2020 19:49:54 |

US3762161

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 11:14:36**

[Interval Dosage Unit Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 18 Nov 2020 19:49:54 |

US3762161

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 11:14:36**

[Interval Dosage Definition \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 18 Nov 2020 19:49:54 |



US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:14:36

[Name of Medication](#)

| Audit                                                                                                                                                                                                          | User                     | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|----------------------|
| DataPoint Verified.                                                                                                                                                                                            | (b) (4), (b) (6)         | 19 Nov 2020 18:06:12 |
| User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)     | 18 Nov 2020 19:51:48 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.                                                                                                      | Coder Import (b) (4)     | 18 Nov 2020 19:51:48 |
| Data point term sent to Coder                                                                                                                                                                                  | System                   | 18 Nov 2020 19:50:49 |
| User entered 'acetaminophen'                                                                                                                                                                                   | Samantha Wheeler (b) (4) | 18 Nov 2020 19:50:42 |
|                                                                                                                                                                                                                | (b) (4)                  |                      |

US3762161

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 11:14:36**

[Prophylaxis](#)

| Audit                 | User                     | Time (GMT)           |
|-----------------------|--------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)         | 19 Nov 2020 18:06:12 |
| User entered 'No (N)' | Samantha Wheeler (b) (4) | 18 Nov 2020 19:50:42 |
|                       | (b) (4)                  |                      |

US3762161

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 11:14:36**

[Indication](#)

| Audit                   | User                     | Time (GMT)           |
|-------------------------|--------------------------|----------------------|
| DataPoint Verified.     | (b) (4), (b) (6)         | 19 Nov 2020 18:06:12 |
| User entered 'headache' | Samantha Wheeler (b) (4) | 18 Nov 2020 19:50:42 |
|                         | (b) (4)                  |                      |

US3762161

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 11:14:36**

[Dose per administration](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 19 Nov 2020 18:06:12 |
| User entered '1000' | Samantha Wheeler (b) (4) | 18 Nov 2020 19:50:42 |
|                     | (b) (4)                  |                      |

US3762161

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 11:14:36**

[Dose unit](#)

| Audit                  | User                     | Time (GMT)           |
|------------------------|--------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)         | 19 Nov 2020 18:06:12 |
| User entered 'mg (mg)' | Samantha Wheeler (b) (4) | 18 Nov 2020 19:50:42 |
|                        | (b) (4)                  |                      |

US3762161

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 11:14:36**

[If dose unit is Other, specify](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 19 Nov 2020 18:06:12 |
| User entered empty. | Samantha Wheeler (b) (4) | 18 Nov 2020 19:50:42 |
|                     | (b) (4)                  |                      |

US3762161

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 11:14:36**

[Frequency](#)

| Audit                          | User                     | Time (GMT)           |
|--------------------------------|--------------------------|----------------------|
| DataPoint Verified.            | (b) (4), (b) (6)         | 19 Nov 2020 18:06:12 |
| User entered 'once daily (QD)' | Samantha Wheeler (b) (4) | 18 Nov 2020 19:50:42 |
|                                | (b) (4)                  |                      |

US3762161

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 11:14:36**

[If frequency is Other, specify](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 19 Nov 2020 18:06:12 |
| User entered empty. | Samantha Wheeler (b) (4) | 18 Nov 2020 19:50:42 |
|                     | (b) (4)                  |                      |



US3762161

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 11:14:36**

[Route of administration](#)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)         | 19 Nov 2020 18:06:12 |
| User entered 'Oral (ORAL)' | Samantha Wheeler (b) (4) | 18 Nov 2020 19:50:42 |
|                            | (b) (4)                  |                      |

US3762161

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 11:14:36**

If route of administration is Other, specify

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 19 Nov 2020 18:06:12 |
| User entered empty. | Samantha Wheeler (b) (4) | 18 Nov 2020 19:50:42 |
|                     | (b) (4)                  |                      |

US3762161

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 11:14:36**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)         | 19 Nov 2020 18:06:12 |
| User entered '10 Nov 2020' | Samantha Wheeler (b) (4) | 18 Nov 2020 19:50:42 |
|                            | (b) (4)                  |                      |

US3762161

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 11:14:36**

[Start date completely unknown](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 19 Nov 2020 18:06:12 |
| User entered '0'    | Samantha Wheeler (b) (4) | 18 Nov 2020 19:50:42 |
|                     | (b) (4)                  |                      |

US3762161

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 11:14:36**

[Ongoing?](#)

| Audit                 | User                     | Time (GMT)           |
|-----------------------|--------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)         | 19 Nov 2020 18:06:12 |
| User entered 'No (N)' | Samantha Wheeler (b) (4) | 18 Nov 2020 19:50:42 |
|                       | (b) (4)                  |                      |

US3762161

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 11:14:36**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)         | 19 Nov 2020 18:06:12 |
| User entered '10 Nov 2020' | Samantha Wheeler (b) (4) | 18 Nov 2020 19:50:42 |
|                            | (b) (4)                  |                      |

US3762161

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 11:14:36**

[Was this medication taken for solicited event?](#)

| Audit                 | User                     | Time (GMT)           |
|-----------------------|--------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)         | 19 Nov 2020 18:06:12 |
| User entered 'No (N)' | Samantha Wheeler (b) (4) | 18 Nov 2020 19:50:42 |
|                       | (b) (4)                  |                      |

US3762161

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 11:14:36**

[Separate Dosage Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 18 Nov 2020 19:50:42 |



US3762161

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 11:14:36**

[Interval Dosage Unit Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 18 Nov 2020 19:50:42 |

US3762161

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 11:14:36**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User   | Time (GMT)           |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 18 Nov 2020 19:50:42 |

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:14:36

[Name of Medication](#)

| Audit                                                                                                                                                                                                                                                                     | User                     | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|----------------------|
| DataPoint Verified.                                                                                                                                                                                                                                                       | (b) (4), (b) (6)         | 19 Nov 2020 18:06:12 |
| 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)     | 18 Nov 2020 19:55:48 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.                                                                                                                                                                 | Coder Import (b) (4)     | 18 Nov 2020 19:55:48 |
| Data point term sent to Coder                                                                                                                                                                                                                                             | System                   | 18 Nov 2020 19:54:53 |
| User entered 'zofran'                                                                                                                                                                                                                                                     | Samantha Wheeler (b) (4) | 18 Nov 2020 19:54:09 |
|                                                                                                                                                                                                                                                                           | (b) (4)                  |                      |

US3762161

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 11:14:36**

[Prophylaxis](#)

| Audit                 | User                     | Time (GMT)           |
|-----------------------|--------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)         | 19 Nov 2020 18:06:12 |
| User entered 'No (N)' | Samantha Wheeler (b) (4) | 18 Nov 2020 19:54:09 |
|                       | (b) (4)                  |                      |

US3762161

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 11:14:36**

[Indication](#)

| Audit                 | User                     | Time (GMT)           |
|-----------------------|--------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)         | 19 Nov 2020 18:06:12 |
| User entered 'nausea' | Samantha Wheeler (b) (4) | 18 Nov 2020 19:54:09 |
|                       | (b) (4)                  |                      |

US3762161

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 11:14:36**

[Dose per administration](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 19 Nov 2020 18:06:12 |
| User entered '4'    | Samantha Wheeler (b) (4) | 18 Nov 2020 19:54:09 |
|                     | (b) (4)                  |                      |

US3762161

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 11:14:36**

[Dose unit](#)

| Audit                  | User                     | Time (GMT)           |
|------------------------|--------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)         | 19 Nov 2020 18:06:12 |
| User entered 'mg (mg)' | Samantha Wheeler (b) (4) | 18 Nov 2020 19:54:09 |
|                        | (b) (4)                  |                      |

US3762161

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 11:14:36**

[If dose unit is Other, specify](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 19 Nov 2020 18:06:12 |
| User entered empty. | Samantha Wheeler (b) (4) | 18 Nov 2020 19:54:09 |
|                     | (b) (4)                  |                      |



US3762161

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 11:14:36**

[Frequency](#)

| Audit                          | User                     | Time (GMT)           |
|--------------------------------|--------------------------|----------------------|
| DataPoint Verified.            | (b) (4), (b) (6)         | 19 Nov 2020 18:06:12 |
| User entered 'once daily (QD)' | Samantha Wheeler (b) (4) | 18 Nov 2020 19:54:09 |
|                                | (b) (4)                  |                      |

US3762161

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 11:14:36**

[If frequency is Other, specify](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 19 Nov 2020 18:06:12 |
| User entered empty. | Samantha Wheeler (b) (4) | 18 Nov 2020 19:54:09 |
|                     | (b) (4)                  |                      |

US3762161

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 11:14:36**

[Route of administration](#)

| Audit                                    | User                     | Time (GMT)           |
|------------------------------------------|--------------------------|----------------------|
| DataPoint Verified.                      | (b) (4), (b) (6)         | 19 Nov 2020 18:06:12 |
| User entered 'Intravenous (INTRAVENOUS)' | Samantha Wheeler (b) (4) | 18 Nov 2020 19:54:09 |
|                                          | (b) (4)                  |                      |

US3762161

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 11:14:36**

If route of administration is Other, specify

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 19 Nov 2020 18:06:12 |
| User entered empty. | Samantha Wheeler (b) (4) | 18 Nov 2020 19:54:09 |
|                     | (b) (4)                  |                      |

US3762161

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 11:14:36**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)         | 19 Nov 2020 18:06:12 |
| User entered '10 Nov 2020' | Samantha Wheeler (b) (4) | 18 Nov 2020 19:54:09 |
|                            | (b) (4)                  |                      |

US3762161

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 11:14:36**

[Start date completely unknown](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 19 Nov 2020 18:06:12 |
| User entered '0'    | Samantha Wheeler (b) (4) | 18 Nov 2020 19:54:09 |
|                     | (b) (4)                  |                      |

US3762161

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 11:14:36**

[Ongoing?](#)

| Audit                 | User                     | Time (GMT)           |
|-----------------------|--------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)         | 19 Nov 2020 18:06:12 |
| User entered 'No (N)' | Samantha Wheeler (b) (4) | 18 Nov 2020 19:54:09 |
|                       | (b) (4)                  |                      |

US3762161

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 11:14:36**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)         | 19 Nov 2020 18:06:12 |
| User entered '10 Nov 2020' | Samantha Wheeler (b) (4) | 18 Nov 2020 19:54:09 |
|                            | (b) (4)                  |                      |



US3762161

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 11:14:36**

[Was this medication taken for solicited event?](#)

| Audit                 | User                     | Time (GMT)           |
|-----------------------|--------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)         | 19 Nov 2020 18:06:12 |
| User entered 'No (N)' | Samantha Wheeler (b) (4) | 18 Nov 2020 19:54:09 |
|                       | (b) (4)                  |                      |

US3762161

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 11:14:36**

[Separate Dosage Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 18 Nov 2020 19:54:09 |

US3762161

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 11:14:36**

[Interval Dosage Unit Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 18 Nov 2020 19:54:09 |

US3762161

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 11:14:36**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User   | Time (GMT)           |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 18 Nov 2020 19:54:09 |

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:14:36

[Name of Medication](#)

| Audit                                                                                                                                                                                                                                                                                       | User                                | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|----------------------|
| DataPoint Verified.                                                                                                                                                                                                                                                                         | (b) (4), (b) (6)                    | 19 Nov 2020 18:06:12 |
| User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: BETA-LACTAM ANTIBACTERIALS, PENICILLINS, ATC: COMBINATIONS OF PENICILLINS, INCL. BETA-LACTAMASE INHIBITORS, PRODUCT: PIPERACILLIN;TAZOBACTAM - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4)     | 18 Nov 2020 19:56:47 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.                                                                                                                                                                                   | Coder Import (b) (4)<br>(b) (4)     | 18 Nov 2020 19:56:47 |
| Data point term sent to Coder                                                                                                                                                                                                                                                               | System                              | 18 Nov 2020 19:55:55 |
| User entered 'piperacillin-tazobactam'                                                                                                                                                                                                                                                      | Samantha Wheeler (b) (4)<br>(b) (4) | 18 Nov 2020 19:55:10 |

US3762161

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 11:14:36**

[Prophylaxis](#)

| Audit                 | User                     | Time (GMT)           |
|-----------------------|--------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)         | 19 Nov 2020 18:06:12 |
| User entered 'No (N)' | Samantha Wheeler (b) (4) | 18 Nov 2020 19:55:10 |
|                       | (b) (4)                  |                      |

US3762161

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 11:14:36**

[Indication](#)

| Audit                    | User                     | Time (GMT)           |
|--------------------------|--------------------------|----------------------|
| DataPoint Verified.      | (b) (4), (b) (6)         | 19 Nov 2020 18:06:12 |
| User entered 'pneumonia' | Samantha Wheeler (b) (4) | 18 Nov 2020 19:55:10 |
|                          | (b) (4)                  |                      |

US3762161

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 11:14:36**

[Dose per administration](#)

| Audit                | User                     | Time (GMT)           |
|----------------------|--------------------------|----------------------|
| DataPoint Verified.  | (b) (4), (b) (6)         | 19 Nov 2020 18:06:12 |
| User entered '3.375' | Samantha Wheeler (b) (4) | 18 Nov 2020 19:55:10 |
|                      | (b) (4)                  |                      |



US3762161

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 11:14:36**

[Dose unit](#)

| Audit                | User                     | Time (GMT)           |
|----------------------|--------------------------|----------------------|
| DataPoint Verified.  | (b) (4), (b) (6)         | 19 Nov 2020 18:06:12 |
| User entered 'g (g)' | Samantha Wheeler (b) (4) | 18 Nov 2020 19:55:10 |
|                      | (b) (4)                  |                      |

US3762161

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 11:14:36**

If dose unit is Other, specify

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 19 Nov 2020 18:06:12 |
| User entered empty. | Samantha Wheeler (b) (4) | 18 Nov 2020 19:55:10 |
|                     | (b) (4)                  |                      |

US3762161

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 11:14:36**

[Frequency](#)

| Audit                                 | User                     | Time (GMT)           |
|---------------------------------------|--------------------------|----------------------|
| DataPoint Verified.                   | (b) (4), (b) (6)         | 19 Nov 2020 18:06:12 |
| User entered 'four times daily (QID)' | Samantha Wheeler (b) (4) | 18 Nov 2020 19:55:10 |
|                                       | (b) (4)                  |                      |

US3762161

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 11:14:36**

[If frequency is Other, specify](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 19 Nov 2020 18:06:12 |
| User entered empty. | Samantha Wheeler (b) (4) | 18 Nov 2020 19:55:10 |
|                     | (b) (4)                  |                      |

US3762161

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 11:14:36**

[Route of administration](#)

| Audit                                    | User                     | Time (GMT)           |
|------------------------------------------|--------------------------|----------------------|
| DataPoint Verified.                      | (b) (4), (b) (6)         | 19 Nov 2020 18:06:12 |
| User entered 'Intravenous (INTRAVENOUS)' | Samantha Wheeler (b) (4) | 18 Nov 2020 19:55:10 |
|                                          | (b) (4)                  |                      |

US3762161

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 11:14:36**

If route of administration is Other, specify

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 19 Nov 2020 18:06:12 |
| User entered empty. | Samantha Wheeler (b) (4) | 18 Nov 2020 19:55:10 |
|                     | (b) (4)                  |                      |

US3762161

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 11:14:36**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)         | 19 Nov 2020 18:06:12 |
| User entered '12 Nov 2020' | Samantha Wheeler (b) (4) | 18 Nov 2020 19:55:10 |
|                            | (b) (4)                  |                      |

US3762161

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 11:14:36**

[Start date completely unknown](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 19 Nov 2020 18:06:12 |
| User entered '0'    | Samantha Wheeler (b) (4) | 18 Nov 2020 19:55:10 |
|                     | (b) (4)                  |                      |



US3762161

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 11:14:36**

[Ongoing?](#)

| Audit                 | User                     | Time (GMT)           |
|-----------------------|--------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)         | 19 Nov 2020 18:06:12 |
| User entered 'No (N)' | Samantha Wheeler (b) (4) | 18 Nov 2020 19:55:10 |
|                       | (b) (4)                  |                      |

US3762161

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 11:14:36**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)         | 19 Nov 2020 18:06:12 |
| User entered '15 Nov 2020' | Samantha Wheeler (b) (4) | 18 Nov 2020 19:55:10 |
|                            | (b) (4)                  |                      |

US3762161

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 11:14:36**

[Was this medication taken for solicited event?](#)

| Audit                 | User                     | Time (GMT)           |
|-----------------------|--------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)         | 19 Nov 2020 18:06:12 |
| User entered 'No (N)' | Samantha Wheeler (b) (4) | 18 Nov 2020 19:55:10 |
|                       | (b) (4)                  |                      |

US3762161

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 11:14:36**

[Separate Dosage Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '4' | System | 18 Nov 2020 19:55:10 |

US3762161

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 11:14:36**

[Interval Dosage Unit Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 18 Nov 2020 19:55:10 |

US3762161

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 11:14:36**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User   | Time (GMT)           |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 18 Nov 2020 19:55:10 |

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:14:36

[Name of Medication](#)

| Audit                                                                                                                                                                                                                     | User                                | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|----------------------|
| DataPoint Verified.                                                                                                                                                                                                       | (b) (4), (b) (6)                    | 19 Nov 2020 18:06:12 |
| User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER ANTIBACTERIALS, ATC: GLYCOPEPTIDE ANTIBACTERIALS, PRODUCT: VANCOMYCIN - version WHODrug-Global-B3\202003. | Coder Import (b) (4)<br>(b) (4)     | 19 Nov 2020 03:36:58 |
| User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\202003.                                                                                                                         | Coder Import (b) (4)<br>(b) (4)     | 19 Nov 2020 03:36:58 |
| Data point term sent to Coder                                                                                                                                                                                             | System                              | 18 Nov 2020 19:55:55 |
| User entered 'vancomycin'                                                                                                                                                                                                 | Samantha Wheeler (b) (4)<br>(b) (4) | 18 Nov 2020 19:55:53 |

US3762161

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 26 Nov 2020 11:14:36**

[Prophylaxis](#)

| Audit                 | User                     | Time (GMT)           |
|-----------------------|--------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)         | 19 Nov 2020 18:06:12 |
| User entered 'No (N)' | Samantha Wheeler (b) (4) | 18 Nov 2020 19:55:53 |
|                       | (b) (4)                  |                      |



US3762161

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 26 Nov 2020 11:14:36**

[Indication](#)

| Audit                    | User                     | Time (GMT)           |
|--------------------------|--------------------------|----------------------|
| DataPoint Verified.      | (b) (4), (b) (6)         | 19 Nov 2020 18:06:12 |
| User entered 'pneumonia' | Samantha Wheeler (b) (4) | 18 Nov 2020 19:55:53 |
|                          | (b) (4)                  |                      |

US3762161

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 26 Nov 2020 11:14:36**

[Dose per administration](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 19 Nov 2020 18:06:12 |
| User entered '1500' | Samantha Wheeler (b) (4) | 18 Nov 2020 19:55:53 |
|                     | (b) (4)                  |                      |

US3762161

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 26 Nov 2020 11:14:36**

[Dose unit](#)

| Audit                  | User                     | Time (GMT)           |
|------------------------|--------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)         | 19 Nov 2020 18:06:12 |
| User entered 'mg (mg)' | Samantha Wheeler (b) (4) | 18 Nov 2020 19:55:53 |
|                        | (b) (4)                  |                      |

US3762161

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 26 Nov 2020 11:14:36**

[If dose unit is Other, specify](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 19 Nov 2020 18:06:12 |
| User entered empty. | Samantha Wheeler (b) (4) | 18 Nov 2020 19:55:53 |
|                     | (b) (4)                  |                      |

US3762161

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 26 Nov 2020 11:14:36**

[Frequency](#)

| Audit                          | User                     | Time (GMT)           |
|--------------------------------|--------------------------|----------------------|
| DataPoint Verified.            | (b) (4), (b) (6)         | 19 Nov 2020 18:06:12 |
| User entered 'once daily (QD)' | Samantha Wheeler (b) (4) | 18 Nov 2020 19:55:53 |
|                                | (b) (4)                  |                      |

US3762161

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 26 Nov 2020 11:14:36**

[If frequency is Other, specify](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 19 Nov 2020 18:06:12 |
| User entered empty. | Samantha Wheeler (b) (4) | 18 Nov 2020 19:55:53 |
|                     | (b) (4)                  |                      |

US3762161

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 26 Nov 2020 11:14:36**

[Route of administration](#)

| Audit                                    | User                     | Time (GMT)           |
|------------------------------------------|--------------------------|----------------------|
| DataPoint Verified.                      | (b) (4), (b) (6)         | 19 Nov 2020 18:06:12 |
| User entered 'Intravenous (INTRAVENOUS)' | Samantha Wheeler (b) (4) | 18 Nov 2020 19:55:53 |
|                                          | (b) (4)                  |                      |

US3762161

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 26 Nov 2020 11:14:36**

If route of administration is Other, specify

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 19 Nov 2020 18:06:12 |
| User entered empty. | Samantha Wheeler (b) (4) | 18 Nov 2020 19:55:53 |
|                     | (b) (4)                  |                      |



US3762161

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 26 Nov 2020 11:14:36**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)         | 19 Nov 2020 18:06:12 |
| User entered '13 Nov 2020' | Samantha Wheeler (b) (4) | 18 Nov 2020 19:55:53 |
|                            | (b) (4)                  |                      |

US3762161

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 26 Nov 2020 11:14:36**

[Start date completely unknown](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 19 Nov 2020 18:06:12 |
| User entered '0'    | Samantha Wheeler (b) (4) | 18 Nov 2020 19:55:53 |
|                     | (b) (4)                  |                      |

US3762161

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 26 Nov 2020 11:14:36**

[Ongoing?](#)

| Audit                 | User                     | Time (GMT)           |
|-----------------------|--------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)         | 19 Nov 2020 18:06:12 |
| User entered 'No (N)' | Samantha Wheeler (b) (4) | 18 Nov 2020 19:55:53 |
|                       | (b) (4)                  |                      |

US3762161

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 26 Nov 2020 11:14:36**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)         | 19 Nov 2020 18:06:12 |
| User entered '15 Nov 2020' | Samantha Wheeler (b) (4) | 18 Nov 2020 19:55:53 |
|                            | (b) (4)                  |                      |

US3762161

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 26 Nov 2020 11:14:36**

[Was this medication taken for solicited event?](#)

| Audit                                                                                  | User                     | Time (GMT)           |
|----------------------------------------------------------------------------------------|--------------------------|----------------------|
| DataPoint Verified.                                                                    | (b) (4), (b) (6)         | 19 Nov 2020 18:06:12 |
| User closed query 'Data is required. Please complete.' (Site from System).             | System                   | 18 Nov 2020 19:55:58 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System                   | 18 Nov 2020 19:55:58 |
| User entered 'No (N)' reason for change: Data Entry Error                              | Samantha Wheeler (b) (4) | 18 Nov 2020 19:55:58 |
| User opened query 'Data is required. Please complete.' (Site from System).             | System                   | 18 Nov 2020 19:55:53 |
| User entered empty.                                                                    | Samantha Wheeler (b) (4) | 18 Nov 2020 19:55:53 |

US3762161

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 26 Nov 2020 11:14:36**

[Separate Dosage Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 18 Nov 2020 19:55:53 |

US3762161

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 26 Nov 2020 11:14:36**

[Interval Dosage Unit Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 18 Nov 2020 19:55:53 |

US3762161

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 26 Nov 2020 11:14:36**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User   | Time (GMT)           |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 18 Nov 2020 19:55:53 |



**US3762161**

**Folder: SAE USA-US130-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 11:14:36**

[SAEID](#)

| Audit                                                 | User             | Time (GMT)           |
|-------------------------------------------------------|------------------|----------------------|
| DataPoint Verified.                                   | (b) (4), (b) (6) | 17 Nov 2020 21:55:37 |
| Reviewed for Safety.                                  | (b) (4), (b) (6) | 12 Nov 2020 15:36:29 |
| User entered<br>'USA-US130-2020-MRNA-1273-P301000001' | System           | 12 Nov 2020 15:35:24 |

**US3762161**

**Folder: SAE USA-US130-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 11:14:36**

**Serious**

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 17 Nov 2020 21:55:37 |
| Reviewed for Safety.   | (b) (4), (b) (6) | 12 Nov 2020 15:36:29 |
| User entered 'Yes (Y)' | System           | 12 Nov 2020 15:35:24 |

**US3762161**

**Folder: SAE USA-US130-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 11:14:36**

[Death](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 17 Nov 2020 21:55:37 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 12 Nov 2020 15:36:29 |
| User entered 'No (N)' | System           | 12 Nov 2020 15:35:24 |

**US3762161**

**Folder: SAE USA-US130-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 11:14:36**

[Life threatening](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 17 Nov 2020 21:55:37 |
| Reviewed for Safety.   | (b) (4), (b) (6) | 12 Nov 2020 15:36:29 |
| User entered 'Yes (Y)' | System           | 12 Nov 2020 15:35:24 |

**US3762161**

**Folder: SAE USA-US130-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 11:14:36**

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 17 Nov 2020 21:55:37 |
| Reviewed for Safety.   | (b) (4), (b) (6) | 12 Nov 2020 15:36:29 |
| User entered 'Yes (Y)' | System           | 12 Nov 2020 15:35:24 |

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:14:36

[Persistent or significant disability or incapacity](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 17 Nov 2020 21:55:37 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 12 Nov 2020 15:36:29 |
| User entered 'No (N)' | System           | 12 Nov 2020 15:35:24 |

**US3762161**

**Folder: SAE USA-US130-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 11:14:36**

[Congenital anomaly or birth defect](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 17 Nov 2020 21:55:37 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 12 Nov 2020 15:36:29 |
| User entered 'No (N)' | System           | 12 Nov 2020 15:35:24 |

**US3762161**

**Folder: SAE USA-US130-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 11:14:36**

[Other medically important event](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 17 Nov 2020 21:55:37 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 12 Nov 2020 15:36:29 |
| User entered 'No (N)' | System           | 12 Nov 2020 15:35:24 |



**US3762161**

**Folder: SAE USA-US130-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 11:14:36**

[Investigator's First Name](#)

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| DataPoint Verified.  | (b) (4), (b) (6) | 17 Nov 2020 21:55:37 |
| Reviewed for Safety. | (b) (4), (b) (6) | 12 Nov 2020 15:36:29 |
| User entered 'John'  | System           | 12 Nov 2020 15:35:24 |

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:14:36

[Investigator's Last Name](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 17 Nov 2020 21:55:37 |
| Reviewed for Safety.   | (b) (4), (b) (6) | 12 Nov 2020 15:36:29 |
| User entered 'Sanders' | System           | 12 Nov 2020 15:35:24 |

**US3762161**

**Folder: SAE USA-US130-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 11:14:36**

[Site Address: Street](#)

| Audit                                  | User             | Time (GMT)           |
|----------------------------------------|------------------|----------------------|
| DataPoint Verified.                    | (b) (4), (b) (6) | 17 Nov 2020 21:55:37 |
| Reviewed for Safety.                   | (b) (4), (b) (6) | 12 Nov 2020 15:36:29 |
| User entered '100 Medical Center Blvd' | System           | 12 Nov 2020 15:35:24 |

**US3762161**

**Folder: SAE USA-US130-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 11:14:36**

[Site Address: City](#)

| Audit                        | User             | Time (GMT)           |
|------------------------------|------------------|----------------------|
| DataPoint Verified.          | (b) (4), (b) (6) | 17 Nov 2020 21:55:37 |
| Reviewed for Safety.         | (b) (4), (b) (6) | 12 Nov 2020 15:36:29 |
| User entered 'Winston-Salem' | System           | 12 Nov 2020 15:35:24 |

**US3762161**

**Folder: SAE USA-US130-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 11:14:36**

[Site Address: State](#)

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| DataPoint Verified.  | (b) (4), (b) (6) | 17 Nov 2020 21:55:37 |
| Reviewed for Safety. | (b) (4), (b) (6) | 12 Nov 2020 15:36:29 |
| User entered 'NC'    | System           | 12 Nov 2020 15:35:24 |

**US3762161**

**Folder: SAE USA-US130-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 11:14:36**

[Site Address: Postal Code](#)

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| DataPoint Verified.  | (b) (4), (b) (6) | 17 Nov 2020 21:55:37 |
| Reviewed for Safety. | (b) (4), (b) (6) | 12 Nov 2020 15:36:29 |
| User entered '27157' | System           | 12 Nov 2020 15:35:24 |

**US3762161**

**Folder: SAE USA-US130-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 11:14:36**

[Investigator Country](#)

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| DataPoint Verified.  | (b) (4), (b) (6) | 17 Nov 2020 21:55:37 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 14:49:46 |
| User entered 'US'    | System           | 12 Nov 2020 15:36:37 |

**US3762161**

**Folder: SAE USA-US130-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 11:14:36**

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '5' | System | 20 Nov 2020 15:40:44 |
| User entered '4' | System | 19 Nov 2020 13:37:07 |
| User entered '3' | System | 18 Nov 2020 15:00:35 |
| User entered '2' | System | 16 Nov 2020 14:50:05 |
| User entered '1' | System | 12 Nov 2020 15:36:37 |



**US3762161**

**Folder: SAE USA-US130-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 11:14:36**

[SAEID](#)

| Audit                                                 | User             | Time (GMT)           |
|-------------------------------------------------------|------------------|----------------------|
| DataPoint Verified.                                   | (b) (4), (b) (6) | 17 Nov 2020 21:55:37 |
| Reviewed for Safety.                                  | (b) (4), (b) (6) | 12 Nov 2020 15:36:29 |
| User entered<br>'USA-US130-2020-MRNA-1273-P301000001' | System           | 12 Nov 2020 15:35:24 |

**US3762161**

**Folder: SAE USA-US130-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 11:14:36**

[Serious](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 17 Nov 2020 21:55:37 |
| Reviewed for Safety.   | (b) (4), (b) (6) | 12 Nov 2020 15:36:29 |
| User entered 'Yes (Y)' | System           | 12 Nov 2020 15:35:24 |

**US3762161**

**Folder: SAE USA-US130-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 11:14:36**

[Death](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 17 Nov 2020 21:55:37 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 12 Nov 2020 15:36:29 |
| User entered 'No (N)' | System           | 12 Nov 2020 15:35:24 |

**US3762161**

**Folder: SAE USA-US130-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 11:14:36**

[Life threatening](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 17 Nov 2020 21:55:37 |
| Reviewed for Safety.   | (b) (4), (b) (6) | 12 Nov 2020 15:36:29 |
| User entered 'Yes (Y)' | System           | 12 Nov 2020 15:35:24 |

**US3762161**

**Folder: SAE USA-US130-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 11:14:36**

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 17 Nov 2020 21:55:37 |
| Reviewed for Safety.   | (b) (4), (b) (6) | 12 Nov 2020 15:36:29 |
| User entered 'Yes (Y)' | System           | 12 Nov 2020 15:35:24 |

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:14:36

[Persistent or significant disability or incapacity](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 17 Nov 2020 21:55:37 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 12 Nov 2020 15:36:29 |
| User entered 'No (N)' | System           | 12 Nov 2020 15:35:24 |

**US3762161**

**Folder: SAE USA-US130-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 11:14:36**

[Congenital anomaly or birth defect](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 17 Nov 2020 21:55:37 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 12 Nov 2020 15:36:29 |
| User entered 'No (N)' | System           | 12 Nov 2020 15:35:24 |

**US3762161**

**Folder: SAE USA-US130-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 11:14:36**

[Other medically important event](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 17 Nov 2020 21:55:37 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 12 Nov 2020 15:36:29 |
| User entered 'No (N)' | System           | 12 Nov 2020 15:35:24 |



**US3762161**

**Folder: SAE USA-US130-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 11:14:36**

[Investigator's First Name](#)

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| DataPoint Verified.  | (b) (4), (b) (6) | 17 Nov 2020 21:55:37 |
| Reviewed for Safety. | (b) (4), (b) (6) | 12 Nov 2020 15:36:29 |
| User entered 'John'  | System           | 12 Nov 2020 15:35:24 |

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:14:36

[Investigator's Last Name](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 17 Nov 2020 21:55:37 |
| Reviewed for Safety.   | (b) (4), (b) (6) | 12 Nov 2020 15:36:29 |
| User entered 'Sanders' | System           | 12 Nov 2020 15:35:24 |

**US3762161**

**Folder: SAE USA-US130-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 11:14:36**

[Site Address: Street](#)

| Audit                                  | User             | Time (GMT)           |
|----------------------------------------|------------------|----------------------|
| DataPoint Verified.                    | (b) (4), (b) (6) | 17 Nov 2020 21:55:37 |
| Reviewed for Safety.                   | (b) (4), (b) (6) | 12 Nov 2020 15:36:29 |
| User entered '100 Medical Center Blvd' | System           | 12 Nov 2020 15:35:24 |

**US3762161**

**Folder: SAE USA-US130-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 11:14:36**

[Site Address: City](#)

| Audit                        | User             | Time (GMT)           |
|------------------------------|------------------|----------------------|
| DataPoint Verified.          | (b) (4), (b) (6) | 17 Nov 2020 21:55:37 |
| Reviewed for Safety.         | (b) (4), (b) (6) | 12 Nov 2020 15:36:29 |
| User entered 'Winston-Salem' | System           | 12 Nov 2020 15:35:24 |

**US3762161**

**Folder: SAE USA-US130-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 11:14:36**

[Site Address: State](#)

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| DataPoint Verified.  | (b) (4), (b) (6) | 17 Nov 2020 21:55:37 |
| Reviewed for Safety. | (b) (4), (b) (6) | 12 Nov 2020 15:36:29 |
| User entered 'NC'    | System           | 12 Nov 2020 15:35:24 |

**US3762161**

**Folder: SAE USA-US130-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 11:14:36**

[Site Address: Postal Code](#)

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| DataPoint Verified.  | (b) (4), (b) (6) | 17 Nov 2020 21:55:37 |
| Reviewed for Safety. | (b) (4), (b) (6) | 12 Nov 2020 15:36:29 |
| User entered '27157' | System           | 12 Nov 2020 15:35:24 |

**US3762161**

**Folder: SAE USA-US130-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 11:14:36**

[Investigator Country](#)

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| DataPoint Verified.  | (b) (4), (b) (6) | 17 Nov 2020 21:55:37 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 14:49:46 |
| User entered 'US'    | System           | 12 Nov 2020 15:36:37 |

**US3762161**

**Folder: SAE USA-US130-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 11:14:36**

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '5' | System | 20 Nov 2020 15:40:44 |
| User entered '4' | System | 19 Nov 2020 13:37:07 |
| User entered '3' | System | 18 Nov 2020 15:00:35 |
| User entered '2' | System | 16 Nov 2020 14:50:05 |
| User entered '1' | System | 12 Nov 2020 15:36:37 |



**US3762161**

**Folder: SAE USA-US130-2020-MRNA-1273-P301000001**

**Form: Safety Report Form (1)**

**Generated On: 26 Nov 2020 11:14:36**

[Date of submission \(Pre-filled from custom function\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| DataPoint Verified.              | (b) (4), (b) (6) | 17 Nov 2020 21:55:37 |
| User entered '12/Nov/2020 15:36' | System           | 12 Nov 2020 15:36:37 |

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 11:14:36

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| DataPoint Verified.  | (b) (4), (b) (6) | 17 Nov 2020 21:55:37 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 14:49:46 |
| User entered '1'     | (b) (4), (b) (6) | 12 Nov 2020 15:36:37 |

**US3762161**

**Folder: SAE USA-US130-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 11:14:36**

[SAEID](#)

| Audit                                                 | User             | Time (GMT)           |
|-------------------------------------------------------|------------------|----------------------|
| DataPoint Verified.                                   | (b) (4), (b) (6) | 17 Nov 2020 21:55:37 |
| Reviewed for Safety.                                  | (b) (4), (b) (6) | 12 Nov 2020 15:36:29 |
| User entered<br>'USA-US130-2020-MRNA-1273-P301000001' | System           | 12 Nov 2020 15:35:24 |

**US3762161**

**Folder: SAE USA-US130-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 11:14:36**

**Serious**

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 17 Nov 2020 21:55:37 |
| Reviewed for Safety.   | (b) (4), (b) (6) | 12 Nov 2020 15:36:29 |
| User entered 'Yes (Y)' | System           | 12 Nov 2020 15:35:24 |

**US3762161**

**Folder: SAE USA-US130-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 11:14:36**

[Death](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 17 Nov 2020 21:55:37 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 12 Nov 2020 15:36:29 |
| User entered 'No (N)' | System           | 12 Nov 2020 15:35:24 |

**US3762161**

**Folder: SAE USA-US130-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 11:14:36**

[Life threatening](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 17 Nov 2020 21:55:37 |
| Reviewed for Safety.   | (b) (4), (b) (6) | 12 Nov 2020 15:36:29 |
| User entered 'Yes (Y)' | System           | 12 Nov 2020 15:35:24 |

**US3762161**

**Folder: SAE USA-US130-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 11:14:36**

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 17 Nov 2020 21:55:37 |
| Reviewed for Safety.   | (b) (4), (b) (6) | 12 Nov 2020 15:36:29 |
| User entered 'Yes (Y)' | System           | 12 Nov 2020 15:35:24 |

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:14:36

[Persistent or significant disability or incapacity](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 17 Nov 2020 21:55:37 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 12 Nov 2020 15:36:29 |
| User entered 'No (N)' | System           | 12 Nov 2020 15:35:24 |



**US3762161**

**Folder: SAE USA-US130-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 11:14:36**

[Congenital anomaly or birth defect](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 17 Nov 2020 21:55:37 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 12 Nov 2020 15:36:29 |
| User entered 'No (N)' | System           | 12 Nov 2020 15:35:24 |

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:14:36

[Other medically important event](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 17 Nov 2020 21:55:37 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 12 Nov 2020 15:36:29 |
| User entered 'No (N)' | System           | 12 Nov 2020 15:35:24 |

**US3762161**

**Folder: SAE USA-US130-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 11:14:36**

[Investigator's First Name](#)

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| DataPoint Verified.  | (b) (4), (b) (6) | 17 Nov 2020 21:55:37 |
| Reviewed for Safety. | (b) (4), (b) (6) | 12 Nov 2020 15:36:29 |
| User entered 'John'  | System           | 12 Nov 2020 15:35:24 |

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:14:36

[Investigator's Last Name](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 17 Nov 2020 21:55:37 |
| Reviewed for Safety.   | (b) (4), (b) (6) | 12 Nov 2020 15:36:29 |
| User entered 'Sanders' | System           | 12 Nov 2020 15:35:24 |

**US3762161**

**Folder: SAE USA-US130-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 11:14:36**

[Site Address: Street](#)

| Audit                                  | User             | Time (GMT)           |
|----------------------------------------|------------------|----------------------|
| DataPoint Verified.                    | (b) (4), (b) (6) | 17 Nov 2020 21:55:37 |
| Reviewed for Safety.                   | (b) (4), (b) (6) | 12 Nov 2020 15:36:29 |
| User entered '100 Medical Center Blvd' | System           | 12 Nov 2020 15:35:24 |

**US3762161**

**Folder: SAE USA-US130-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 11:14:36**

[Site Address: City](#)

| Audit                        | User             | Time (GMT)           |
|------------------------------|------------------|----------------------|
| DataPoint Verified.          | (b) (4), (b) (6) | 17 Nov 2020 21:55:37 |
| Reviewed for Safety.         | (b) (4), (b) (6) | 12 Nov 2020 15:36:29 |
| User entered 'Winston-Salem' | System           | 12 Nov 2020 15:35:24 |

**US3762161**

**Folder: SAE USA-US130-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 11:14:36**

[Site Address: State](#)

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| DataPoint Verified.  | (b) (4), (b) (6) | 17 Nov 2020 21:55:37 |
| Reviewed for Safety. | (b) (4), (b) (6) | 12 Nov 2020 15:36:29 |
| User entered 'NC'    | System           | 12 Nov 2020 15:35:24 |

**US3762161**

**Folder: SAE USA-US130-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 11:14:36**

[Site Address: Postal Code](#)

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| DataPoint Verified.  | (b) (4), (b) (6) | 17 Nov 2020 21:55:37 |
| Reviewed for Safety. | (b) (4), (b) (6) | 12 Nov 2020 15:36:29 |
| User entered '27157' | System           | 12 Nov 2020 15:35:24 |



**US3762161**

**Folder: SAE USA-US130-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 11:14:36**

[Investigator Country](#)

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| DataPoint Verified.  | (b) (4), (b) (6) | 17 Nov 2020 21:55:37 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 14:49:46 |
| User entered 'US'    | System           | 12 Nov 2020 15:36:37 |

**US3762161**

**Folder: SAE USA-US130-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 11:14:36**

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '5' | System | 20 Nov 2020 15:40:44 |
| User entered '4' | System | 19 Nov 2020 13:37:07 |
| User entered '3' | System | 18 Nov 2020 15:00:35 |
| User entered '2' | System | 16 Nov 2020 14:50:05 |
| User entered '1' | System | 12 Nov 2020 15:36:37 |

**US3762161**

**Folder: SAE USA-US130-2020-MRNA-1273-P301000001**

**Form: Safety Report Form (2)**

**Generated On: 26 Nov 2020 11:14:36**

[Date of submission \(Pre-filled from custom function\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| DataPoint Verified.              | (b) (4), (b) (6) | 17 Nov 2020 21:55:37 |
| User entered '16/Nov/2020 09:49' | System           | 16 Nov 2020 14:50:05 |

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 11:14:36

**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 15:00:04 |
| DataPoint Verified.  | (b) (4), (b) (6) | 17 Nov 2020 21:55:37 |
| User entered '1'     | (b) (4), (b) (6) | 16 Nov 2020 14:50:05 |

**US3762161**

**Folder: SAE USA-US130-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 11:14:36**

[SAEID](#)

| Audit                                                 | User             | Time (GMT)           |
|-------------------------------------------------------|------------------|----------------------|
| DataPoint Verified.                                   | (b) (4), (b) (6) | 17 Nov 2020 21:55:37 |
| Reviewed for Safety.                                  | (b) (4), (b) (6) | 12 Nov 2020 15:36:29 |
| User entered<br>'USA-US130-2020-MRNA-1273-P301000001' | System           | 12 Nov 2020 15:35:24 |

**US3762161**

**Folder: SAE USA-US130-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 11:14:36**

**Serious**

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 17 Nov 2020 21:55:37 |
| Reviewed for Safety.   | (b) (4), (b) (6) | 12 Nov 2020 15:36:29 |
| User entered 'Yes (Y)' | System           | 12 Nov 2020 15:35:24 |

**US3762161**

**Folder: SAE USA-US130-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 11:14:36**

[Death](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 17 Nov 2020 21:55:37 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 12 Nov 2020 15:36:29 |
| User entered 'No (N)' | System           | 12 Nov 2020 15:35:24 |

**US3762161**

**Folder: SAE USA-US130-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 11:14:36**

[Life threatening](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 17 Nov 2020 21:55:37 |
| Reviewed for Safety.   | (b) (4), (b) (6) | 12 Nov 2020 15:36:29 |
| User entered 'Yes (Y)' | System           | 12 Nov 2020 15:35:24 |



**US3762161**

**Folder: SAE USA-US130-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 11:14:36**

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 17 Nov 2020 21:55:37 |
| Reviewed for Safety.   | (b) (4), (b) (6) | 12 Nov 2020 15:36:29 |
| User entered 'Yes (Y)' | System           | 12 Nov 2020 15:35:24 |

**US3762161**

**Folder: SAE USA-US130-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 11:14:36**

[Persistent or significant disability or incapacity](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 17 Nov 2020 21:55:37 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 12 Nov 2020 15:36:29 |
| User entered 'No (N)' | System           | 12 Nov 2020 15:35:24 |

**US3762161**

**Folder: SAE USA-US130-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 11:14:36**

[Congenital anomaly or birth defect](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 17 Nov 2020 21:55:37 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 12 Nov 2020 15:36:29 |
| User entered 'No (N)' | System           | 12 Nov 2020 15:35:24 |

**US3762161**

**Folder: SAE USA-US130-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 11:14:36**

[Other medically important event](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 17 Nov 2020 21:55:37 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 12 Nov 2020 15:36:29 |
| User entered 'No (N)' | System           | 12 Nov 2020 15:35:24 |

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:14:36

[Investigator's First Name](#)

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| DataPoint Verified.  | (b) (4), (b) (6) | 17 Nov 2020 21:55:37 |
| Reviewed for Safety. | (b) (4), (b) (6) | 12 Nov 2020 15:36:29 |
| User entered 'John'  | System           | 12 Nov 2020 15:35:24 |

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:14:36

[Investigator's Last Name](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 17 Nov 2020 21:55:37 |
| Reviewed for Safety.   | (b) (4), (b) (6) | 12 Nov 2020 15:36:29 |
| User entered 'Sanders' | System           | 12 Nov 2020 15:35:24 |

**US3762161**

**Folder: SAE USA-US130-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 11:14:36**

[Site Address: Street](#)

| Audit                                  | User             | Time (GMT)           |
|----------------------------------------|------------------|----------------------|
| DataPoint Verified.                    | (b) (4), (b) (6) | 17 Nov 2020 21:55:37 |
| Reviewed for Safety.                   | (b) (4), (b) (6) | 12 Nov 2020 15:36:29 |
| User entered '100 Medical Center Blvd' | System           | 12 Nov 2020 15:35:24 |

**US3762161**

**Folder: SAE USA-US130-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 11:14:36**

[Site Address: City](#)

| Audit                        | User             | Time (GMT)           |
|------------------------------|------------------|----------------------|
| DataPoint Verified.          | (b) (4), (b) (6) | 17 Nov 2020 21:55:37 |
| Reviewed for Safety.         | (b) (4), (b) (6) | 12 Nov 2020 15:36:29 |
| User entered 'Winston-Salem' | System           | 12 Nov 2020 15:35:24 |



**US3762161**

**Folder: SAE USA-US130-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 11:14:36**

[Site Address: State](#)

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| DataPoint Verified.  | (b) (4), (b) (6) | 17 Nov 2020 21:55:37 |
| Reviewed for Safety. | (b) (4), (b) (6) | 12 Nov 2020 15:36:29 |
| User entered 'NC'    | System           | 12 Nov 2020 15:35:24 |

**US3762161**

**Folder: SAE USA-US130-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 11:14:36**

[Site Address: Postal Code](#)

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| DataPoint Verified.  | (b) (4), (b) (6) | 17 Nov 2020 21:55:37 |
| Reviewed for Safety. | (b) (4), (b) (6) | 12 Nov 2020 15:36:29 |
| User entered '27157' | System           | 12 Nov 2020 15:35:24 |

**US3762161**

**Folder: SAE USA-US130-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 11:14:36**

[Investigator Country](#)

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| DataPoint Verified.  | (b) (4), (b) (6) | 17 Nov 2020 21:55:37 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 14:49:46 |
| User entered 'US'    | System           | 12 Nov 2020 15:36:37 |

**US3762161**

**Folder: SAE USA-US130-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 11:14:36**

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '5' | System | 20 Nov 2020 15:40:44 |
| User entered '4' | System | 19 Nov 2020 13:37:07 |
| User entered '3' | System | 18 Nov 2020 15:00:35 |
| User entered '2' | System | 16 Nov 2020 14:50:05 |
| User entered '1' | System | 12 Nov 2020 15:36:37 |

**US3762161**

**Folder: SAE USA-US130-2020-MRNA-1273-P301000001**

**Form: Safety Report Form (3)**

**Generated On: 26 Nov 2020 11:14:36**

[Date of submission \(Pre-filled from custom function\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| DataPoint Verified.              | (b) (4), (b) (6) | 18 Nov 2020 15:58:38 |
| User entered '18/Nov/2020 15:00' | System           | 18 Nov 2020 15:00:35 |

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 11:14:36

**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) | 19 Nov 2020 13:36:39 |
| DataPoint Verified.  | (b) (4), (b) (6) | 18 Nov 2020 15:58:38 |
| User entered '1'     | (b) (4), (b) (6) | 18 Nov 2020 15:00:35 |

**US3762161**

**Folder: SAE USA-US130-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 11:14:36**

[SAEID](#)

| Audit                                                 | User             | Time (GMT)           |
|-------------------------------------------------------|------------------|----------------------|
| DataPoint Verified.                                   | (b) (4), (b) (6) | 17 Nov 2020 21:55:37 |
| Reviewed for Safety.                                  | (b) (4), (b) (6) | 12 Nov 2020 15:36:29 |
| User entered<br>'USA-US130-2020-MRNA-1273-P301000001' | System           | 12 Nov 2020 15:35:24 |

**US3762161**

**Folder: SAE USA-US130-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 11:14:36**

**Serious**

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 17 Nov 2020 21:55:37 |
| Reviewed for Safety.   | (b) (4), (b) (6) | 12 Nov 2020 15:36:29 |
| User entered 'Yes (Y)' | System           | 12 Nov 2020 15:35:24 |



**US3762161**

**Folder: SAE USA-US130-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 11:14:36**

[Death](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 17 Nov 2020 21:55:37 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 12 Nov 2020 15:36:29 |
| User entered 'No (N)' | System           | 12 Nov 2020 15:35:24 |

**US3762161**

**Folder: SAE USA-US130-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 11:14:36**

[Life threatening](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 17 Nov 2020 21:55:37 |
| Reviewed for Safety.   | (b) (4), (b) (6) | 12 Nov 2020 15:36:29 |
| User entered 'Yes (Y)' | System           | 12 Nov 2020 15:35:24 |

**US3762161**

**Folder: SAE USA-US130-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 11:14:36**

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 17 Nov 2020 21:55:37 |
| Reviewed for Safety.   | (b) (4), (b) (6) | 12 Nov 2020 15:36:29 |
| User entered 'Yes (Y)' | System           | 12 Nov 2020 15:35:24 |

**US3762161**

**Folder: SAE USA-US130-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 11:14:36**

[Persistent or significant disability or incapacity](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 17 Nov 2020 21:55:37 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 12 Nov 2020 15:36:29 |
| User entered 'No (N)' | System           | 12 Nov 2020 15:35:24 |

**US3762161**

**Folder: SAE USA-US130-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 11:14:36**

[Congenital anomaly or birth defect](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 17 Nov 2020 21:55:37 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 12 Nov 2020 15:36:29 |
| User entered 'No (N)' | System           | 12 Nov 2020 15:35:24 |

**US3762161**

**Folder: SAE USA-US130-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 11:14:36**

[Other medically important event](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 17 Nov 2020 21:55:37 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 12 Nov 2020 15:36:29 |
| User entered 'No (N)' | System           | 12 Nov 2020 15:35:24 |

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:14:36

[Investigator's First Name](#)

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| DataPoint Verified.  | (b) (4), (b) (6) | 17 Nov 2020 21:55:37 |
| Reviewed for Safety. | (b) (4), (b) (6) | 12 Nov 2020 15:36:29 |
| User entered 'John'  | System           | 12 Nov 2020 15:35:24 |

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:14:36

[Investigator's Last Name](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 17 Nov 2020 21:55:37 |
| Reviewed for Safety.   | (b) (4), (b) (6) | 12 Nov 2020 15:36:29 |
| User entered 'Sanders' | System           | 12 Nov 2020 15:35:24 |



**US3762161**

**Folder: SAE USA-US130-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 11:14:36**

[Site Address: Street](#)

| Audit                                  | User             | Time (GMT)           |
|----------------------------------------|------------------|----------------------|
| DataPoint Verified.                    | (b) (4), (b) (6) | 17 Nov 2020 21:55:37 |
| Reviewed for Safety.                   | (b) (4), (b) (6) | 12 Nov 2020 15:36:29 |
| User entered '100 Medical Center Blvd' | System           | 12 Nov 2020 15:35:24 |

**US3762161**

**Folder: SAE USA-US130-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 11:14:36**

[Site Address: City](#)

| Audit                        | User             | Time (GMT)           |
|------------------------------|------------------|----------------------|
| DataPoint Verified.          | (b) (4), (b) (6) | 17 Nov 2020 21:55:37 |
| Reviewed for Safety.         | (b) (4), (b) (6) | 12 Nov 2020 15:36:29 |
| User entered 'Winston-Salem' | System           | 12 Nov 2020 15:35:24 |

**US3762161**

**Folder: SAE USA-US130-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 11:14:36**

[Site Address: State](#)

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| DataPoint Verified.  | (b) (4), (b) (6) | 17 Nov 2020 21:55:37 |
| Reviewed for Safety. | (b) (4), (b) (6) | 12 Nov 2020 15:36:29 |
| User entered 'NC'    | System           | 12 Nov 2020 15:35:24 |

**US3762161**

**Folder: SAE USA-US130-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 11:14:36**

[Site Address: Postal Code](#)

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| DataPoint Verified.  | (b) (4), (b) (6) | 17 Nov 2020 21:55:37 |
| Reviewed for Safety. | (b) (4), (b) (6) | 12 Nov 2020 15:36:29 |
| User entered '27157' | System           | 12 Nov 2020 15:35:24 |

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:14:36

[Investigator Country](#)

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| DataPoint Verified.  | (b) (4), (b) (6) | 17 Nov 2020 21:55:37 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 14:49:46 |
| User entered 'US'    | System           | 12 Nov 2020 15:36:37 |

**US3762161**

**Folder: SAE USA-US130-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 11:14:36**

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '5' | System | 20 Nov 2020 15:40:44 |
| User entered '4' | System | 19 Nov 2020 13:37:07 |
| User entered '3' | System | 18 Nov 2020 15:00:35 |
| User entered '2' | System | 16 Nov 2020 14:50:05 |
| User entered '1' | System | 12 Nov 2020 15:36:37 |

**US3762161**

**Folder: SAE USA-US130-2020-MRNA-1273-P301000001**

**Form: Safety Report Form (4)**

**Generated On: 26 Nov 2020 11:14:36**

[Date of submission \(Pre-filled from custom function\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| DataPoint Verified.              | (b) (4), (b) (6) | 19 Nov 2020 18:05:16 |
| User entered '19/Nov/2020 13:36' | System           | 19 Nov 2020 13:37:07 |

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form (4)

Generated On: 26 Nov 2020 11:14:36

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 19 Nov 2020 18:05:16 |
| User entered '1'    | (b) (4), (b) (6) | 19 Nov 2020 13:37:07 |



**US3762161**

**Folder: SAE USA-US130-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 11:14:36**

[SAEID](#)

| Audit                                                 | User             | Time (GMT)           |
|-------------------------------------------------------|------------------|----------------------|
| DataPoint Verified.                                   | (b) (4), (b) (6) | 17 Nov 2020 21:55:37 |
| Reviewed for Safety.                                  | (b) (4), (b) (6) | 12 Nov 2020 15:36:29 |
| User entered<br>'USA-US130-2020-MRNA-1273-P301000001' | System           | 12 Nov 2020 15:35:24 |

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:14:36

Serious

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 17 Nov 2020 21:55:37 |
| Reviewed for Safety.   | (b) (4), (b) (6) | 12 Nov 2020 15:36:29 |
| User entered 'Yes (Y)' | System           | 12 Nov 2020 15:35:24 |

**US3762161**

**Folder: SAE USA-US130-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 11:14:36**

[Death](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 17 Nov 2020 21:55:37 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 12 Nov 2020 15:36:29 |
| User entered 'No (N)' | System           | 12 Nov 2020 15:35:24 |

**US3762161**

**Folder: SAE USA-US130-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 11:14:36**

[Life threatening](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 17 Nov 2020 21:55:37 |
| Reviewed for Safety.   | (b) (4), (b) (6) | 12 Nov 2020 15:36:29 |
| User entered 'Yes (Y)' | System           | 12 Nov 2020 15:35:24 |

**US3762161**

**Folder: SAE USA-US130-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 11:14:36**

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 17 Nov 2020 21:55:37 |
| Reviewed for Safety.   | (b) (4), (b) (6) | 12 Nov 2020 15:36:29 |
| User entered 'Yes (Y)' | System           | 12 Nov 2020 15:35:24 |

**US3762161**

**Folder: SAE USA-US130-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 11:14:36**

[Persistent or significant disability or incapacity](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 17 Nov 2020 21:55:37 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 12 Nov 2020 15:36:29 |
| User entered 'No (N)' | System           | 12 Nov 2020 15:35:24 |

**US3762161**

**Folder: SAE USA-US130-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 11:14:36**

[Congenital anomaly or birth defect](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 17 Nov 2020 21:55:37 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 12 Nov 2020 15:36:29 |
| User entered 'No (N)' | System           | 12 Nov 2020 15:35:24 |

**US3762161**

**Folder: SAE USA-US130-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 11:14:36**

[Other medically important event](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 17 Nov 2020 21:55:37 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 12 Nov 2020 15:36:29 |
| User entered 'No (N)' | System           | 12 Nov 2020 15:35:24 |



**US3762161**

**Folder: SAE USA-US130-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 11:14:36**

[Investigator's First Name](#)

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| DataPoint Verified.  | (b) (4), (b) (6) | 17 Nov 2020 21:55:37 |
| Reviewed for Safety. | (b) (4), (b) (6) | 12 Nov 2020 15:36:29 |
| User entered 'John'  | System           | 12 Nov 2020 15:35:24 |

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:14:36

[Investigator's Last Name](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 17 Nov 2020 21:55:37 |
| Reviewed for Safety.   | (b) (4), (b) (6) | 12 Nov 2020 15:36:29 |
| User entered 'Sanders' | System           | 12 Nov 2020 15:35:24 |

**US3762161**

**Folder: SAE USA-US130-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 11:14:36**

[Site Address: Street](#)

| Audit                                  | User             | Time (GMT)           |
|----------------------------------------|------------------|----------------------|
| DataPoint Verified.                    | (b) (4), (b) (6) | 17 Nov 2020 21:55:37 |
| Reviewed for Safety.                   | (b) (4), (b) (6) | 12 Nov 2020 15:36:29 |
| User entered '100 Medical Center Blvd' | System           | 12 Nov 2020 15:35:24 |

**US3762161**

**Folder: SAE USA-US130-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 11:14:36**

[Site Address: City](#)

| Audit                        | User             | Time (GMT)           |
|------------------------------|------------------|----------------------|
| DataPoint Verified.          | (b) (4), (b) (6) | 17 Nov 2020 21:55:37 |
| Reviewed for Safety.         | (b) (4), (b) (6) | 12 Nov 2020 15:36:29 |
| User entered 'Winston-Salem' | System           | 12 Nov 2020 15:35:24 |

**US3762161**

**Folder: SAE USA-US130-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 11:14:36**

[Site Address: State](#)

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| DataPoint Verified.  | (b) (4), (b) (6) | 17 Nov 2020 21:55:37 |
| Reviewed for Safety. | (b) (4), (b) (6) | 12 Nov 2020 15:36:29 |
| User entered 'NC'    | System           | 12 Nov 2020 15:35:24 |

**US3762161**

**Folder: SAE USA-US130-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 11:14:36**

[Site Address: Postal Code](#)

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| DataPoint Verified.  | (b) (4), (b) (6) | 17 Nov 2020 21:55:37 |
| Reviewed for Safety. | (b) (4), (b) (6) | 12 Nov 2020 15:36:29 |
| User entered '27157' | System           | 12 Nov 2020 15:35:24 |

**US3762161**

**Folder: SAE USA-US130-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 11:14:36**

[Investigator Country](#)

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| DataPoint Verified.  | (b) (4), (b) (6) | 17 Nov 2020 21:55:37 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 14:49:46 |
| User entered 'US'    | System           | 12 Nov 2020 15:36:37 |

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:14:36

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '5' | System | 20 Nov 2020 15:40:44 |
| User entered '4' | System | 19 Nov 2020 13:37:07 |
| User entered '3' | System | 18 Nov 2020 15:00:35 |
| User entered '2' | System | 16 Nov 2020 14:50:05 |
| User entered '1' | System | 12 Nov 2020 15:36:37 |



**US3762161**

**Folder: SAE USA-US130-2020-MRNA-1273-P301000001**

**Form: Safety Report Form (5)**

**Generated On: 26 Nov 2020 11:14:36**

[Date of submission \(Pre-filled from custom function\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| DataPoint Verified.              | (b) (4), (b) (6) | 24 Nov 2020 18:46:53 |
| User entered '20/Nov/2020 10:40' | System           | 20 Nov 2020 15:40:44 |

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form (5)

Generated On: 26 Nov 2020 11:14:36

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 24 Nov 2020 18:46:53 |
| User entered '1'    | (b) (4), (b) (6) | 20 Nov 2020 15:40:44 |
|                     |                  |                      |
|                     |                  |                      |