

US3802074 (Prod: UPMC University Center)

Generated By: KC Joubran

Generated On: 10 Jun 2021 09:55:48

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US3802074

Form: Participant Creation

Data signed: (b) (4) 28 Jan 2021 18:19:30

Generated On: 10 Jun 2021 09:55:48

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[Participant ID](#)

US3802074

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

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US3802074

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 28 Jan 2021 18:19:30

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

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 28 Jan 2021 18:19:30

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|   |  |
|---|--|
| Date of Birth (MMM yyyy)                  | (b) (6) 1950   |
| Age                                       | 69   |
| Age Units                                 | YEARS  |
| Age (Derived)                             | 69   |
| 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

Data signed: (b) (4) 28 Jan 2021 18:19:30

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

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 28 Jan 2021 18:19:30

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 28 Jan 2021 18:19:30

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Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 28 Jan 2021 18:19:30

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|   |  |
|---|--|
| Condition   | SEASONAL ALLERGIES   |
| Start date (dd MMM yyyy)                          |  |
| Start date completely unknown                     | True   |
| 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)                    |  |
| Start Year (derived)                              |  |
| Stop Month and Year (derived)                     |  |
| Stop Year (derived)                               |  |



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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 28 Jan 2021 18:19:30

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

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 28 Jan 2021 18:19:30

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

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 28 Jan 2021 18:19:30

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|                                     |  |
|-------------------------------------|--|
| Were vital signs assessed?          | Yes <input checked="" type="radio"/>   |
|                                     | No <input type="radio"/>               |
| Date of assessment (dd MMM yyyy)    | 31 AUG 2020                            |
| Time of assessment (00:00-23:59)    | 09:08 (24 HR)                          |
| Vital Signs Date and Time (derived) | 31 AUG 2020 09:08                      |
| Height (xxx.x)                      | 181 cm                                 |
| Weight (xxx.x)                      | 218 lb                                 |
| BMI (xxx.x)                         | 30.24661 kg/m <sup>2</sup>             |
| BMI units                           | KG/M2                                  |
| Temperature (xxx.x)                 | 96.6 F                                 |
| Route of measurement                | Oral <input type="radio"/>             |
|                                     | Axillary <input type="radio"/>         |
|                                     | Other <input checked="" type="radio"/> |
| If Other, specify                   | INFRARED                               |
| Pulse (xxx)                         | 65 beats/min                           |
| Pulse units                         | BPM                                    |
| Respiratory Rate (xxx)              | 18 breaths/min                         |
| Respiratory Rate units              | BREATHS/MIN                            |
| Systolic Blood Pressure (xxx)       | 146 mmHg                               |
| Systolic Blood Pressure units       | MMHG                                   |
| Diastolic Blood Pressure (xxx)      | 81 mmHg                                |
| Diastolic Blood Pressure units      | MMHG                                   |
| Height (derived)                    |  |
| Weight (derived)                    |  |

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 28 Jan 2021 18:19:30

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Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

31 AUG 2020

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 28 Jan 2021 18:19:30

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**Occupational Risk**

**Healthcare workers** (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers) Yes ☐ No ☒

**Emergency Response** (e.g., Law enforcement officers, Firefighters, emergency medical service workers) Yes ☐ No ☒

**Retail or Restaurant Operations**, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores) Yes ☐ No ☒

**Manufacturing & Production Operations** with inherent overcrowding (e.g., factory workers, meat/food processing plants) Yes ☐ No ☒

**Warehouse shipping and fulfillment centers** and jobs (e.g., Amazon facilities) Yes ☐ No ☒

**Transportation and delivery services** (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers) Yes ☐ No ☒

**Border Protection and Military Personnel** (e.g., TSA, custom and border protection agents, military personnel not social distancing) Yes ☐ No ☒

**Personal Care and in-home services** (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services) Yes ☐ No ☒

**Hospitality and Tourism Workers** (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts) Yes ☐ No ☒

**Pastoral, Social or Public Health Workers** requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy) Yes ☐ No ☒

**Educators and Students** (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting) Yes ☐ No ☒

**Other** Yes ☒ No ☐

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**Specify** (b) (6)

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

**No Risk Identified** False

**Resides in Nursing Home or Assisted Living Facility** False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 28 Jan 2021 18:19:30

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|  |       |
|--|-------|
| <b>Resides in Multi-family dwelling</b> (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs) | False |
| <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)  | True  |
| <b>Other</b>   | False |
| <b>Specify</b>   |       |

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 28 Jan 2021 18:19:30

Generated On: 10 Jun 2021 09:55:48

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

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 28 Jan 2021 18:19:30

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

What was the participant's randomization number? 188918

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

Data signed: (b) (4) 28 Jan 2021 18:19:30

Generated On: 10 Jun 2021 09:55:48

|        |        |
|--------|--------|
| Height | 181 cm |
| Weight | 218 lb |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 28 Jan 2021 18:19:30

Generated On: 10 Jun 2021 09:55:48

|                                     |  |
|-------------------------------------|--|
| Height                              | 181 cm   |
| Weight                              | 218 lb   |
| Timepoint                           | Pre-Dose <input checked="" type="radio"/><br>Post-Dose <input type="radio"/>                           |
| Were vital signs assessed?          | Yes <input checked="" type="radio"/><br>No <input type="radio"/>                                       |
| Date of assessment (dd MMM yyyy)    | 31 AUG 2020  |
| Time of assessment (00:00-23:59)    | 09:08 (24 HR)  |
| Vital Signs Date and Time (derived) | 31 AUG 2020 09:08  |
| Temperature (xxx.x)                 | 96.6 F   |
| Route of measurement                | Oral <input type="radio"/><br>Axillary <input type="radio"/><br>Other <input checked="" type="radio"/> |
| If Other, specify                   | INFRARED   |
| Pulse (xxx)                         | 65 beats/min   |
| Pulse units                         | BPM  |
| Respiratory Rate (xxx)              | 18 breaths/min   |
| Respiratory Rate units              | BREATHS/MIN  |
| Systolic Blood Pressure (xxx)       | 146 mmHg   |
| Systolic Blood Pressure units       | MMHG   |
| Diastolic Blood Pressure (xxx)      | 81 mmHg  |
| Diastolic Blood Pressure units      | MMHG   |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 28 Jan 2021 18:19:30

Generated On: 10 Jun 2021 09:55:48

|                                     |  |
|-------------------------------------|--|
| Height                              | 181 cm   |
| Weight                              | 218 lb   |
| Timepoint                           | Pre-Dose <input type="radio"/><br>Post-Dose <input checked="" type="radio"/>                           |
| Were vital signs assessed?          | Yes <input checked="" type="radio"/><br>No <input type="radio"/>                                       |
| Date of assessment (dd MMM yyyy)    | 31 AUG 2020  |
| Time of assessment (00:00-23:59)    | 10:19 (24 HR)  |
| Vital Signs Date and Time (derived) | 31 AUG 2020 10:19  |
| Temperature (xxx.x)                 | 96.7 F   |
| Route of measurement                | Oral <input type="radio"/><br>Axillary <input type="radio"/><br>Other <input checked="" type="radio"/> |
| If Other, specify                   | INFRARED   |
| Pulse (xxx)                         | 62 beats/min   |
| Pulse units                         | BPM  |
| Respiratory Rate (xxx)              | 20 breaths/min   |
| Respiratory Rate units              | BREATHS/MIN  |
| Systolic Blood Pressure (xxx)       | 148 mmHg   |
| Systolic Blood Pressure units       | MMHG   |
| Diastolic Blood Pressure (xxx)      | 92 mmHg  |
| Diastolic Blood Pressure units      | MMHG   |

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 28 Jan 2021 18:19:30

Generated On: 10 Jun 2021 09:55:48

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

31 AUG 2020

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 28 Jan 2021 18:19:30

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Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

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

What was the treatment time? (00:00-23:59) 09:45 (24 HR)

Treatment Date and Time (derived) 31 AUG 2020 09:45

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 28 Jan 2021 18:19:30

Generated On: 10 Jun 2021 09:55:48

|                                    |                                      |
|------------------------------------|--------------------------------------|
| Was the sample collected?          | Yes <input checked="" type="radio"/> |
|                                    | No <input type="radio"/>             |
| Collection date (dd MMM yyyy)      | 31 AUG 2020                          |
| Collection time (00:00-23:59)      | 09:23 (24 HR)                        |
| Collection date and time (derived) | 31 AUG 2020 09:23                    |

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 28 Jan 2021 18:19:30

Generated On: 10 Jun 2021 09:55:48

|                               |                           |                                 |                                    |
|-------------------------------|---------------------------|---------------------------------|------------------------------------|
| Collection date (dd MMM yyyy) |                           |                                 | 31 AUG 2020                        |
| Lab Test                      | Was the sample collected? | Collection time (00:00 - 23:59) | Collection date and time (derived) |
| Nasopharyngeal Swab 1         | Yes                       | 09:28                           | 31 AUG 2020 09:28                  |
| Nasopharyngeal Swab 2         | No                        |                                 |                                    |

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 28 Jan 2021 18:19:30

Generated On: 10 Jun 2021 09:55:48

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: 10 Jun 2021 09:55:48

**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

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

31 AUG 2020 10:21

PC Open Date & Time

31 AUG 2020 10:05

PC Close Date & Time

31 AUG 2020 12:35

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:55:48

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.9 °F

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

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

|                      |                   |
|----------------------|-------------------|
| PC Time Stamp        | 31 AUG 2020 19:19 |
| PC Open Date & Time  | 31 AUG 2020 13:30 |
| PC Close Date & Time | 01 SEP 2020 11:59 |

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:55:48

**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 98.1 °F

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

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

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

To **PREVENT** pain or fever from occurring False

PC Time Stamp 01 SEP 2020 19:00

PC Open Date & Time 01 SEP 2020 12:00

PC Close Date & Time 02 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:55:48

**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

97.1 °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

02 SEP 2020 22:09

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:55:48

**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

97.1 °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

03 SEP 2020 18:42

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3802074

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:55:48

**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.1 °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

04 SEP 2020 19:36

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3802074

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:55:48

**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

05 SEP 2020 18:45

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3802074

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:55:48

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °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):

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

06 SEP 2020 18:42

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59



US3802074

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(8)

Generated On: 10 Jun 2021 09:55:48

**TIMEPOINT**

DAY 8

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

07 SEP 2020 17:29

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3802074

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:55:48

**TIMEPOINT**

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

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

31 AUG 2020 10:21

PC Open Date & Time

31 AUG 2020 10:05

PC Close Date & Time

31 AUG 2020 12:35

US3802074

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:55:48

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

Please select one response below

None ☐

Does not interfere with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

31 AUG 2020 19:20

PC Open Date & Time

31 AUG 2020 13:30

PC Close Date & Time

01 SEP 2020 11:59

US3802074

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:55:48

**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

01 SEP 2020 19:02

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3802074

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:55:48

**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

02 SEP 2020 22:10

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3802074

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:55:48

**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

03 SEP 2020 18:43

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3802074

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:55:48

**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 SEP 2020 19:37

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3802074

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:55:48

**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

05 SEP 2020 18:45

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59



US3802074

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:55:48

**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 SEP 2020 18:42

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3802074

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:55:48

**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 ☐

US3802074

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:55:48

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

No ☒

Yes ☐

|                      |                   |
|----------------------|-------------------|
| PC Time stamp        | 31 AUG 2020 10:22 |
| PC Open Date & Time  | 31 AUG 2020 10:05 |
| PC Close Date & Time | 31 AUG 2020 12:35 |

US3802074

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:55:48

**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 ☐

US3802074

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:55:48

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

No ☒

Yes ☐

|                      |                   |
|----------------------|-------------------|
| PC Time stamp        | 31 AUG 2020 19:20 |
| PC Open Date & Time  | 31 AUG 2020 13:30 |
| PC Close Date & Time | 01 SEP 2020 11:59 |

US3802074

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:55:48

**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 ☒

US3802074

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:55:48

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 01 SEP 2020 19:03 |
| PC Open Date & Time          | 01 SEP 2020 12:00 |
| PC Close Date & Time         | 02 SEP 2020 11:59 |

US3802074

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:55:48

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 ☒

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Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:55:48

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 02 SEP 2020 22:10 |
| PC Open Date & Time          | 02 SEP 2020 12:00 |
| PC Close Date & Time         | 03 SEP 2020 11:59 |

US3802074

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:55:48

**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 ☒

US3802074

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:55:48

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 03 SEP 2020 18:43 |
| PC Open Date & Time          | 03 SEP 2020 12:00 |
| PC Close Date & Time         | 04 SEP 2020 11:59 |

US3802074

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:55:48

**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 ☒

PRODUCTION RELEASE (v12.003

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US3802074

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:55:48

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 04 SEP 2020 19:37 |
| PC Open Date & Time          | 04 SEP 2020 12:00 |
| PC Close Date & Time         | 05 SEP 2020 11:59 |

US3802074

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:55:48

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 ☒

US3802074

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:55:48

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 05 SEP 2020 18:45 |
| PC Open Date & Time          | 05 SEP 2020 12:00 |
| PC Close Date & Time         | 06 SEP 2020 11:59 |

US3802074

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:55:48

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 ☒



US3802074

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:55:48

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 06 SEP 2020 18:43 |
| PC Open Date & Time          | 06 SEP 2020 12:00 |
| PC Close Date & Time         | 07 SEP 2020 11:59 |

US3802074

Folder: Diary Dose 1 (1)

Form: Headache\_Day(8)

Generated On: 10 Jun 2021 09:55:48

**TIMEPOINT**

DAY 8

Select one response below to indicate the intensity of your

None ☒

**HEADACHE**

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 ☐

PC Time Stamp

07 SEP 2020 17:30

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3802074

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(8)

Generated On: 10 Jun 2021 09:55:48

---

**TIMEPOINT**

DAY 8

Select one response below to indicate the intensity of your

None ☒

**FATIGUE**

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

---

PC Time Stamp

07 SEP 2020 17:30

---

PC Open Date & Time

07 SEP 2020 12:00

---

PC Close Date & Time

08 SEP 2020 11:59

---

US3802074

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(8)

Generated On: 10 Jun 2021 09:55:48

**TIMEPOINT**

DAY 8

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

None ☒

**ACHES ALL OVER BODY**

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 07 SEP 2020 17:30

PC Open Date & Time 07 SEP 2020 12:00

PC Close Date & Time 08 SEP 2020 11:59

US3802074

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(8)

Generated On: 10 Jun 2021 09:55:48

**TIMEPOINT**

DAY 8

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

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

PC Time stamp 07 SEP 2020 17:30

PC Open Date & Time 07 SEP 2020 12:00

PC Close Date & Time 08 SEP 2020 11:59

US3802074

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 10 Jun 2021 09:55:48

|   |  |
|---|--|
| <b>TIMEPOINT</b>  | DAY 8  |
| Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms? | No <input checked="" type="radio"/><br>Yes <input type="radio"/> |
| PC Time stamp   | 07 SEP 2020 17:30  |
| PC Open Date & Time   | 07 SEP 2020 12:00  |
| PC Close Date & Time  | 08 SEP 2020 11:59  |

US3802074

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 07 Sep 2020 19:27:15

Generated On: 10 Jun 2021 09:55:48

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

7 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3802074

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 07 Sep 2020 19:27:41

Generated On: 10 Jun 2021 09:55:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3802074

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 28 Jan 2021 18:19:30

Generated On: 10 Jun 2021 09:55:48

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*

US3802074

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 28 Jan 2021 18:19:30

Generated On: 10 Jun 2021 09:55:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3802074

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 28 Jan 2021 18:19:30

Generated On: 10 Jun 2021 09:55:48

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3802074

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 28 Jan 2021 18:19:30

Generated On: 10 Jun 2021 09:55:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3802074

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 28 Jan 2021 18:19:30

Generated On: 10 Jun 2021 09:55:48

|   |   |
|---|---|
| Was this visit performed?                                       | Yes <input checked="" type="radio"/>    |
|   | No <input type="radio"/>                |
| Visit date (dd MMM yyyy)  | 28 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                                  |

US3802074

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 28 Jan 2021 18:19:30

Generated On: 10 Jun 2021 09:55:48

|                                     |   |
|-------------------------------------|---|
| 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)    | 28 SEP 2020                               |
| Time of assessment (00:00-23:59)    | 09:05 (24 HR)                             |
| Vital Signs Date and Time (derived) | 28 SEP 2020 09:05                         |
| Temperature (xxx.x)                 | 96.3 F                                    |
| Route of measurement                | Oral <input type="radio"/>                |
|                                     | Axillary <input type="radio"/>            |
|                                     | Other <input checked="" type="radio"/>    |
| If Other, specify                   | INFRARED                                  |
| Pulse (xxx)                         | 66 beats/min                              |
| Pulse units                         | BPM                                       |
| Respiratory Rate (xxx)              | 18 breaths/min                            |
| Respiratory Rate units              | BREATHS/MIN                               |
| Systolic Blood Pressure (xxx)       | 153 mmHg                                  |
| Systolic Blood Pressure units       | MMHG                                      |
| Diastolic Blood Pressure (xxx)      | 92 mmHg                                   |
| Diastolic Blood Pressure units      | MMHG                                      |

US3802074

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 28 Jan 2021 18:19:30

Generated On: 10 Jun 2021 09:55:48

|                                     |  |
|-------------------------------------|--|
| 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)    | 28 SEP 2020                                |
| Time of assessment (00:00-23:59)    | 09:56 (24 HR)                              |
| Vital Signs Date and Time (derived) | 28 SEP 2020 09:56                          |
| Temperature (xxx.x)                 | 96.8 F                                     |
| Route of measurement                | Oral <input type="radio"/>                 |
|                                     | Axillary <input type="radio"/>             |
|                                     | Other <input checked="" type="radio"/>     |
| If Other, specify                   | INFRARED                                   |
| Pulse (xxx)                         | 66 beats/min                               |
| Pulse units                         | BPM  |
| Respiratory Rate (xxx)              | 18 breaths/min                             |
| Respiratory Rate units              | BREATHS/MIN                                |
| Systolic Blood Pressure (xxx)       | 155 mmHg                                   |
| Systolic Blood Pressure units       | MMHG                                       |
| Diastolic Blood Pressure (xxx)      | 93 mmHg                                    |
| Diastolic Blood Pressure units      | MMHG                                       |

US3802074

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 28 Jan 2021 18:19:30

Generated On: 10 Jun 2021 09:55:48

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.*



US3802074

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 28 Jan 2021 18:19:30

Generated On: 10 Jun 2021 09:55:48

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 28 SEP 2020

What was the treatment time? (00:00-23:59) 09:26 (24 HR)

Treatment Date and Time (derived) 28 SEP 2020 09:26

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

What was the frequency of the study treatment dosing? ONCE

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

US3802074

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 28 Jan 2021 18:19:30

Generated On: 10 Jun 2021 09:55:48

|                           |                                      |
|---------------------------|--------------------------------------|
| Was the sample collected? | Yes <input checked="" type="radio"/> |
|                           | No <input type="radio"/>             |

|                               |             |
|-------------------------------|-------------|
| Collection date (dd MMM yyyy) | 28 SEP 2020 |
|-------------------------------|-------------|

|                               |               |
|-------------------------------|---------------|
| Collection time (00:00-23:59) | 09:13 (24 HR) |
|-------------------------------|---------------|

|                                    |                   |
|------------------------------------|-------------------|
| Collection date and time (derived) | 28 SEP 2020 09:13 |
|------------------------------------|-------------------|

US3802074

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 28 Jan 2021 18:19:30

Generated On: 10 Jun 2021 09:55:48

|                               |                           |                                 |                                    |
|-------------------------------|---------------------------|---------------------------------|------------------------------------|
| Collection date (dd MMM yyyy) |                           |                                 | 28 SEP 2020                        |
| Lab Test                      | Was the sample collected? | Collection time (00:00 - 23:59) | Collection date and time (derived) |
| Nasopharyngeal Swab 1         | Yes                       | 09:10                           | 28 SEP 2020 09:10                  |
| Nasopharyngeal Swab 2         | No                        |                                 |                                    |

US3802074

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 28 Jan 2021 18:19:30

Generated On: 10 Jun 2021 09:55:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3802074

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:55:48

**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

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

28 SEP 2020 09:58

PC Open Date & Time

28 SEP 2020 09:46

PC Close Date & Time

28 SEP 2020 12:16

US3802074

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:55:48

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.7 °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        | 28 SEP 2020 18:10 |
| PC Open Date & Time  | 28 SEP 2020 13:11 |
| PC Close Date & Time | 29 SEP 2020 11:59 |

US3802074

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:55:48

**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):

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

To **PREVENT** pain or fever from occurring False

PC Time Stamp 29 SEP 2020 17:01

PC Open Date & Time 29 SEP 2020 12:00

PC Close Date & Time 30 SEP 2020 11:59

US3802074

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:55:48

**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

97.1 °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

30 SEP 2020 17:30

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59



US3802074

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:55:48

**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):

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

01 OCT 2020 19:02

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3802074

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:55:48

**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

02 OCT 2020 17:20

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3802074

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:55:48

**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

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

03 OCT 2020 17:05

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3802074

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:55:48

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °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 22:30

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3802074

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:55:48

**TIMEPOINT**

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

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

28 SEP 2020 09:58

PC Open Date & Time

28 SEP 2020 09:46

PC Close Date & Time

28 SEP 2020 12:16

US3802074

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:55:48

**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

28 SEP 2020 18:10

PC Open Date & Time

28 SEP 2020 13:11

PC Close Date & Time

29 SEP 2020 11:59

US3802074

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:55:48

**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

29 SEP 2020 17:02

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3802074

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:55:48

**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

30 SEP 2020 17:30

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59



US3802074

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:55:48

**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

01 OCT 2020 19:03

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3802074

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:55:48

**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

02 OCT 2020 17:20

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3802074

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:55:48

**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

03 OCT 2020 17:05

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3802074

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:55:48

**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

04 OCT 2020 22:31

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3802074

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:55:48

**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 ☐

US3802074

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:55:48

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

No ☒

Yes ☐

|                      |                   |
|----------------------|-------------------|
| PC Time stamp        | 28 SEP 2020 09:59 |
| PC Open Date & Time  | 28 SEP 2020 09:46 |
| PC Close Date & Time | 28 SEP 2020 12:16 |

US3802074

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:55:48

**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 ☐

US3802074

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:55:48

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

No ☒

Yes ☐

|                      |                   |
|----------------------|-------------------|
| PC Time stamp        | 28 SEP 2020 18:11 |
| PC Open Date & Time  | 28 SEP 2020 13:11 |
| PC Close Date & Time | 29 SEP 2020 11:59 |



US3802074

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:55:48

**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 ☒

US3802074

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:55:48

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 29 SEP 2020 17:02 |
| PC Open Date & Time          | 29 SEP 2020 12:00 |
| PC Close Date & Time         | 30 SEP 2020 11:59 |

US3802074

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:55:48

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 ☒

US3802074

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:55:48

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 30 SEP 2020 17:31 |
| PC Open Date & Time          | 30 SEP 2020 12:00 |
| PC Close Date & Time         | 01 OCT 2020 11:59 |

US3802074

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:55:48

**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 ☒

US3802074

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:55:48

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 01 OCT 2020 19:03 |
| PC Open Date & Time          | 01 OCT 2020 12:00 |
| PC Close Date & Time         | 02 OCT 2020 11:59 |

US3802074

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:55:48

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 ☒

US3802074

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:55:48

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 02 OCT 2020 17:21 |
| PC Open Date & Time          | 02 OCT 2020 12:00 |
| PC Close Date & Time         | 03 OCT 2020 11:59 |



US3802074

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:55:48

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 ☒

US3802074

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:55:48

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 03 OCT 2020 17:05 |
| PC Open Date & Time          | 03 OCT 2020 12:00 |
| PC Close Date & Time         | 04 OCT 2020 11:59 |

US3802074

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:55:48

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 ☒

US3802074

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:55:48

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 04 OCT 2020 22:31 |
| PC Open Date & Time          | 04 OCT 2020 12:00 |
| PC Close Date & Time         | 05 OCT 2020 11:59 |

US3802074

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 28 Jan 2021 18:19:30

Generated On: 10 Jun 2021 09:55:48

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

5 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3802074

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 28 Jan 2021 18:19:30

Generated On: 10 Jun 2021 09:55:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3802074

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 28 Jan 2021 18:19:30

Generated On: 10 Jun 2021 09:55:48

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3802074

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 28 Jan 2021 18:19:30

Generated On: 10 Jun 2021 09:55:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3802074

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 28 Jan 2021 18:19:30

Generated On: 10 Jun 2021 09:55:48

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3802074

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 28 Jan 2021 18:19:30

Generated On: 10 Jun 2021 09:55:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3802074

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 28 Jan 2021 18:19:30

Generated On: 10 Jun 2021 09:55:48

|   |   |
|---|---|
| Was this visit performed?                                       | Yes <input checked="" type="radio"/>    |
|   | No <input type="radio"/>                |
| Visit date (dd MMM yyyy)  | 22 OCT 2020                             |
| Was visit performed at the participant's home or at the clinic? | Home <input type="radio"/>              |
|   | Clinic <input checked="" type="radio"/> |
| Folder OID  | VISIT3                                  |

US3802074

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 28 Jan 2021 18:19:30

Generated On: 10 Jun 2021 09:55:48

|                                     |  |
|-------------------------------------|--|
| Were vital signs assessed?          | Yes <input checked="" type="radio"/>   |
|                                     | No <input type="radio"/>               |
| Date of assessment (dd MMM yyyy)    | 22 OCT 2020                            |
| Time of assessment (00:00-23:59)    | 08:22 (24 HR)                          |
| Vital Signs Date and Time (derived) | 22 OCT 2020 08:22                      |
| Temperature (xxx.x)                 | 97.9 F                                 |
| Route of measurement                | Oral <input type="radio"/>             |
|                                     | Axillary <input type="radio"/>         |
|                                     | Other <input checked="" type="radio"/> |
| If Other, specify                   | INFRARED                               |
| Pulse (xxx)                         | 63 beats/min                           |
| Pulse units                         | BPM                                    |
| Respiratory Rate (xxx)              | 18 breaths/min                         |
| Respiratory Rate units              | BREATHS/MIN                            |
| Systolic Blood Pressure (xxx)       | 151 mmHg                               |
| Systolic Blood Pressure units       | MMHG                                   |
| Diastolic Blood Pressure (xxx)      | 89 mmHg                                |
| Diastolic Blood Pressure units      | MMHG                                   |
| Height (derived)                    |  |
| Weight (derived)                    |  |

US3802074

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 28 Jan 2021 18:19:30

Generated On: 10 Jun 2021 09:55:48

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.*

US3802074

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 28 Jan 2021 18:19:30

Generated On: 10 Jun 2021 09:55:48

|                                    |                                      |
|------------------------------------|--------------------------------------|
| Was the sample collected?          | Yes <input checked="" type="radio"/> |
|                                    | No <input type="radio"/>             |
| Collection date (dd MMM yyyy)      | 22 OCT 2020                          |
| Collection time (00:00-23:59)      | 08:31 (24 HR)                        |
| Collection date and time (derived) | 22 OCT 2020 08:31                    |

US3802074

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 28 Jan 2021 18:19:30

Generated On: 10 Jun 2021 09:55:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3802074

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:48

**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

31 OCT 2020 00:01:46

Patient Cloud Open Date & Time

31 OCT 2020 00:01

Patient Cloud Close Date & Time

04 NOV 2020 23:59



US3802074

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:48

**TIMEPOINT**

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

07 NOV 2020 09:35:21

Patient Cloud Open Date & Time

07 NOV 2020 00:01

Patient Cloud Close Date & Time

11 NOV 2020 23:59

US3802074

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:48

**TIMEPOINT**

DAY 78

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

16 NOV 2020 07:22:28

Patient Cloud Open Date & Time

14 NOV 2020 00:01

Patient Cloud Close Date & Time

18 NOV 2020 23:59

US3802074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:48

| 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="checkbox"/><br>Yes <input type="checkbox"/>  |
| Have you been exposed to someone with known SARS-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="checkbox"/><br>Yes <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="checkbox"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Please identify below 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="checkbox"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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18 NOV 2020 00:01

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[Patient Cloud Close Date & Time](#)

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22 NOV 2020 23:59

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US3802074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:48

| 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="checkbox"/><br>Yes <input type="checkbox"/>  |
| Have you been exposed to someone with known SARS-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="checkbox"/><br>Yes <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="checkbox"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Please identify below 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="checkbox"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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25 NOV 2020 00:01

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[Patient Cloud Close Date & Time](#)

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29 NOV 2020 23:59

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US3802074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:48

| 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 checked="" type="radio"/><br>Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/><br>Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |  |
| Date and time of submission   | 04 DEC 2020 13:54:04   |
| Patient Cloud Open Date & Time  | 02 DEC 2020 00:01  |
| Patient Cloud Close Date & Time   | 06 DEC 2020 23:59  |

US3802074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:48

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

Date and time of submission

09 DEC 2020 08:41:48

Patient Cloud Open Date & Time

09 DEC 2020 00:01

Patient Cloud Close Date & Time

13 DEC 2020 23:59



US3802074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:48

**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 ☒

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

19 DEC 2020 17:59:51

Patient Cloud Open Date & Time

16 DEC 2020 00:01

Patient Cloud Close Date & Time

20 DEC 2020 23:59

US3802074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:48

**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 ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

25 DEC 2020 23:10:38

Patient Cloud Open Date & Time

23 DEC 2020 00:01

Patient Cloud Close Date & Time

27 DEC 2020 23:59

US3802074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:48

**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 ☒

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

01 JAN 2021 12:02:38

Patient Cloud Open Date & Time

30 DEC 2020 00:01

Patient Cloud Close Date & Time

03 JAN 2021 23:59

US3802074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:48

**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 ☒

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

06 JAN 2021 23:20:35

Patient Cloud Open Date & Time

06 JAN 2021 00:01

Patient Cloud Close Date & Time

10 JAN 2021 23:59

US3802074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:48

| 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 checked="" type="radio"/><br>Yes <input type="radio"/>   |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input checked="" type="radio"/>   |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |  |
| Date and time of submission   | 15 JAN 2021 12:01:12   |
| Patient Cloud Open Date & Time  | 13 JAN 2021 00:01  |
| Patient Cloud Close Date & Time   | 17 JAN 2021 23:59  |

US3802074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:48

**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 ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

22 JAN 2021 13:54:59

Patient Cloud Open Date & Time

20 JAN 2021 00:01

Patient Cloud Close Date & Time

24 JAN 2021 23:59

US3802074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:48

**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 ☒

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

27 JAN 2021 08:55:51

Patient Cloud Open Date & Time

27 JAN 2021 00:01

Patient Cloud Close Date & Time

31 JAN 2021 23:59

US3802074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:48

**TIMEPOINT**

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

05 FEB 2021 12:00:49

Patient Cloud Open Date & Time

03 FEB 2021 00:01

Patient Cloud Close Date & Time

07 FEB 2021 23:59



US3802074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:48

**TIMEPOINT**

DAY 166

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

10 FEB 2021 21:10:24

Patient Cloud Open Date & Time

10 FEB 2021 00:01

Patient Cloud Close Date & Time

14 FEB 2021 23:59

US3802074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:48

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

Date and time of submission

17 FEB 2021 07:32:53

Patient Cloud Open Date & Time

17 FEB 2021 00:01

Patient Cloud Close Date & Time

21 FEB 2021 23:59

US3802074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:48

**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 ☒

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

24 FEB 2021 11:25:48

Patient Cloud Open Date & Time

24 FEB 2021 00:01

Patient Cloud Close Date & Time

28 FEB 2021 23:59

US3802074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:48

**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 ☒

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

07 MAR 2021 12:20:02

Patient Cloud Open Date & Time

03 MAR 2021 00:01

Patient Cloud Close Date & Time

07 MAR 2021 23:59

US3802074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:48

**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 ☒

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

12 MAR 2021 11:31:03

Patient Cloud Open Date & Time

10 MAR 2021 00:01

Patient Cloud Close Date & Time

14 MAR 2021 23:59

US3802074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:48

| 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 checked="" type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/><br>Yes <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input checked="" type="radio"/><br>Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |  |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?  | No <input checked="" type="radio"/><br>Yes <input type="radio"/> |
| Date and time of submission   | 17 MAR 2021 20:50:24   |
| Patient Cloud Open Date & Time  | 17 MAR 2021 00:01  |
| Patient Cloud Close Date & Time   | 21 MAR 2021 23:59  |

US3802074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:48

**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 ☒

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

26 MAR 2021 12:01:12

Patient Cloud Open Date & Time

24 MAR 2021 00:01

Patient Cloud Close Date & Time

28 MAR 2021 23:59

US3802074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:48

| 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 checked="" type="radio"/>   |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/><br>Yes <input type="radio"/>   |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input checked="" type="radio"/><br>Yes <input type="radio"/>   |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |  |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="radio"/><br>Yes <input checked="" type="radio"/>   |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/> |
| Date and time of submission   | 31 MAR 2021 07:02:08   |
| Patient Cloud Open Date & Time  | 31 MAR 2021 00:01  |
| Patient Cloud Close Date & Time   | 04 APR 2021 23:59  |



US3802074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:48

**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 ☒

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

07 APR 2021 06:25:22

Patient Cloud Open Date & Time

07 APR 2021 00:01

Patient Cloud Close Date & Time

11 APR 2021 23:59

US3802074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:48

**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 ☒

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

14 APR 2021 07:38:13

Patient Cloud Open Date & Time

14 APR 2021 00:01

Patient Cloud Close Date & Time

18 APR 2021 23:59

US3802074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:48

| 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 checked="" type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/><br>Yes <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input checked="" type="radio"/><br>Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |  |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?  | No <input checked="" type="radio"/><br>Yes <input type="radio"/> |
| Date and time of submission   | 24 APR 2021 17:13:02   |
| Patient Cloud Open Date & Time  | 21 APR 2021 00:01  |
| Patient Cloud Close Date & Time   | 25 APR 2021 23:59  |

US3802074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:48

**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 ☒

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

29 APR 2021 10:54:30

Patient Cloud Open Date & Time

28 APR 2021 00:01

Patient Cloud Close Date & Time

02 MAY 2021 23:59

US3802074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:48

| 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="checkbox"/><br>Yes <input type="checkbox"/>  |
| Have you been exposed to someone with known SARS-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="checkbox"/><br>Yes <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="checkbox"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Please identify below 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="checkbox"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

05 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

09 MAY 2021 23:59

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US3802074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:48

**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 ☐  
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 ☐

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

12 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

16 MAY 2021 23:59

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US3802074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:48

| 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="checkbox"/><br>Yes <input type="checkbox"/>  |
| Have you been exposed to someone with known SARS-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="checkbox"/><br>Yes <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="checkbox"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Please identify below 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="checkbox"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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19 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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23 MAY 2021 23:59

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US3802074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:48

**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 ☐  
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 ☐

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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26 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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30 MAY 2021 23:59

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US3802074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:48

| 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="checkbox"/><br>Yes <input type="checkbox"/>  |
| Have you been exposed to someone with known SARS-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="checkbox"/><br>Yes <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="checkbox"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Please identify below 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="checkbox"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

02 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

06 JUN 2021 23:59

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US3802074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:48

| 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="checkbox"/><br>Yes <input type="checkbox"/>  |
| Have you been exposed to someone with known SARS-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="checkbox"/><br>Yes <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="checkbox"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Please identify below 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="checkbox"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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09 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

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13 JUN 2021 23:59

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US3802074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:48

**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 ☐  
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 ☐

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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16 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

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20 JUN 2021 23:59

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US3802074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:48

| 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="checkbox"/><br>Yes <input type="checkbox"/>  |
| Have you been exposed to someone with known SARS-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="checkbox"/><br>Yes <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="checkbox"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Please identify below 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="checkbox"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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23 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

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27 JUN 2021 23:59

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US3802074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:48

**TIMEPOINT**

DAY 306

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

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

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

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

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

Fever (Temperature  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐  
Chills ☐  
Cough ☐  
Shortness of breath ☐  
Difficulty breathing ☐  
Fatigue ☐  
Muscle aches ☐  
Body aches ☐  
Headache ☐  
New loss of taste ☐  
New loss of smell ☐  
Sore throat ☐  
Congestion ☐  
Runny nose ☐  
Nausea ☐  
Vomiting ☐  
Diarrhea ☐

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

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

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

30 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

04 JUL 2021 23:59

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US3802074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:48

**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 ☐  
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 ☐

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

07 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

11 JUL 2021 23:59

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US3802074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:48

| 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="checkbox"/><br>Yes <input type="checkbox"/>  |
| Have you been exposed to someone with known SARS-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="checkbox"/><br>Yes <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="checkbox"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |  |
| Fever (Temperature $\geq$ 100.4°F/38°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="checkbox"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

|   |                   |
|---|-------------------|
| Date and time of submission                         |                   |
| <a href="#">Patient Cloud Open Date &amp; Time</a>  | 14 JUL 2021 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 18 JUL 2021 23:59 |

US3802074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:48

**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 ☐  
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 ☐

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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21 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

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25 JUL 2021 23:59

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US3802074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:48

| 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="checkbox"/><br>Yes <input type="checkbox"/>  |
| Have you been exposed to someone with known SARS-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="checkbox"/><br>Yes <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="checkbox"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Please identify below 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="checkbox"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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28 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

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01 AUG 2021 23:59

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US3802074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:48

| 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"/>   |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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04 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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08 AUG 2021 23:59

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US3802074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:48

| 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="checkbox"/><br>Yes <input type="checkbox"/>  |
| Have you been exposed to someone with known SARS-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="checkbox"/><br>Yes <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="checkbox"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Please identify below 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="checkbox"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

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Date and time of submission

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|  |                   |
|--|-------------------|
| <a href="#">Patient Cloud Open Date &amp; Time</a> | 11 AUG 2021 00:01 |
|--|-------------------|

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|   |                   |
|---|-------------------|
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 15 AUG 2021 23:59 |
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US3802074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:48

**TIMEPOINT**

DAY 355

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

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

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

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

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

Fever (Temperature  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐  
Chills ☐  
Cough ☐  
Shortness of breath ☐  
Difficulty breathing ☐  
Fatigue ☐  
Muscle aches ☐  
Body aches ☐  
Headache ☐  
New loss of taste ☐  
New loss of smell ☐  
Sore throat ☐  
Congestion ☐  
Runny nose ☐  
Nausea ☐  
Vomiting ☐  
Diarrhea ☐

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

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

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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18 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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22 AUG 2021 23:59

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US3802074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:48

**TIMEPOINT**

DAY 362

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°F/38°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 ☐

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

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Date and time of submission

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|  |                   |
|--|-------------------|
| <a href="#">Patient Cloud Open Date &amp; Time</a> | 25 AUG 2021 00:01 |
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|   |                   |
|---|-------------------|
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 29 AUG 2021 23:59 |
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US3802074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:48

**TIMEPOINT**

DAY 369

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

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

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

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

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

Fever (Temperature  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐  
Chills ☐  
Cough ☐  
Shortness of breath ☐  
Difficulty breathing ☐  
Fatigue ☐  
Muscle aches ☐  
Body aches ☐  
Headache ☐  
New loss of taste ☐  
New loss of smell ☐  
Sore throat ☐  
Congestion ☐  
Runny nose ☐  
Nausea ☐  
Vomiting ☐  
Diarrhea ☐

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

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

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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01 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

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05 SEP 2021 23:59

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US3802074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:48

**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 ☐  
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 ☐

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

08 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

12 SEP 2021 23:59

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US3802074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:48

**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 ☐

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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15 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

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19 SEP 2021 23:59

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US3802074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:48

**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 ☐  
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 ☐

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

22 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

26 SEP 2021 23:59

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US3802074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:48

**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 ☐

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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29 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

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03 OCT 2021 23:59

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US3802074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:48

| 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="checkbox"/><br>Yes <input type="checkbox"/>  |
| Have you been exposed to someone with known SARS-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="checkbox"/><br>Yes <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="checkbox"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Please identify below 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="checkbox"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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06 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

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10 OCT 2021 23:59

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US3802074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:48

| 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"/>   |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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13 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

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17 OCT 2021 23:59

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US3802074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:48

**TIMEPOINT**

DAY 418

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

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

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

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

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

Fever (Temperature  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐  
Chills ☐  
Cough ☐  
Shortness of breath ☐  
Difficulty breathing ☐  
Fatigue ☐  
Muscle aches ☐  
Body aches ☐  
Headache ☐  
New loss of taste ☐  
New loss of smell ☐  
Sore throat ☐  
Congestion ☐  
Runny nose ☐  
Nausea ☐  
Vomiting ☐  
Diarrhea ☐

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

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

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

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Date and time of submission

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|  |                   |
|--|-------------------|
| <a href="#">Patient Cloud Open Date &amp; Time</a> | 20 OCT 2021 00:01 |
|--|-------------------|

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|   |                   |
|---|-------------------|
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 24 OCT 2021 23:59 |
|---|-------------------|

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US3802074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:48

**TIMEPOINT**

DAY 425

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

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

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

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

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

Fever (Temperature  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐  
Chills ☐  
Cough ☐  
Shortness of breath ☐  
Difficulty breathing ☐  
Fatigue ☐  
Muscle aches ☐  
Body aches ☐  
Headache ☐  
New loss of taste ☐  
New loss of smell ☐  
Sore throat ☐  
Congestion ☐  
Runny nose ☐  
Nausea ☐  
Vomiting ☐  
Diarrhea ☐

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

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

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

31 OCT 2021 23:59



US3802074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:48

**TIMEPOINT**

DAY 432

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

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

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

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

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

Fever (Temperature  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐  
Chills ☐  
Cough ☐  
Shortness of breath ☐  
Difficulty breathing ☐  
Fatigue ☐  
Muscle aches ☐  
Body aches ☐  
Headache ☐  
New loss of taste ☐  
New loss of smell ☐  
Sore throat ☐  
Congestion ☐  
Runny nose ☐  
Nausea ☐  
Vomiting ☐  
Diarrhea ☐

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

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

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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03 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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07 NOV 2021 23:59

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US3802074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:48

**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 ☐  
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 ☐

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

10 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

14 NOV 2021 23:59

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US3802074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:48

| 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="checkbox"/><br>Yes <input type="checkbox"/>  |
| Have you been exposed to someone with known SARS-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="checkbox"/><br>Yes <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="checkbox"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Please identify below 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="checkbox"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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17 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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21 NOV 2021 23:59

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US3802074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:48

**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 ☐

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

28 NOV 2021 23:59



US3802074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:48

| 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="checkbox"/><br>Yes <input type="checkbox"/>  |
| Have you been exposed to someone with known SARS-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="checkbox"/><br>Yes <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="checkbox"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Please identify below 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="checkbox"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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01 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

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05 DEC 2021 23:59

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US3802074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:48

| 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="checkbox"/><br>Yes <input type="checkbox"/>  |
| Have you been exposed to someone with known SARS-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="checkbox"/><br>Yes <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="checkbox"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Please identify below 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="checkbox"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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08 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

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12 DEC 2021 23:59

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US3802074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:48

**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 ☐  
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 ☐

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

|   |                   |
|---|-------------------|
| Date and time of submission                         |                   |
| <a href="#">Patient Cloud Open Date &amp; Time</a>  | 15 DEC 2021 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 19 DEC 2021 23:59 |

US3802074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:48

| 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"/>   |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

|   |                   |
|---|-------------------|
| Date and time of submission                         |                   |
| <a href="#">Patient Cloud Open Date &amp; Time</a>  | 22 DEC 2021 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 26 DEC 2021 23:59 |



US3802074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:48

| 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="checkbox"/><br>Yes <input type="checkbox"/>  |
| Have you been exposed to someone with known SARS-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="checkbox"/><br>Yes <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="checkbox"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Please identify below 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="checkbox"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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29 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

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02 JAN 2022 23:59

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US3802074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:48

| 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="checkbox"/><br>Yes <input type="checkbox"/>  |
| Have you been exposed to someone with known SARS-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="checkbox"/><br>Yes <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="checkbox"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Please identify below 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="checkbox"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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05 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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09 JAN 2022 23:59

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US3802074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:48

**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 ☐

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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12 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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16 JAN 2022 23:59

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US3802074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:48

**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 ☐

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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19 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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23 JAN 2022 23:59

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US3802074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:48

**TIMEPOINT**

DAY 516

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

No ☐  
Yes ☐

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

No ☐  
Yes ☐

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

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

No ☐  
Yes ☐

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

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

Chills

Cough

Shortness of breath

Difficulty breathing

Fatigue

Muscle aches

Body aches

Headache

New loss of taste

New loss of smell

Sore throat

Congestion

Runny nose

Nausea

Vomiting

Diarrhea

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

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

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

No ☐  
Yes ☐

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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26 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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30 JAN 2022 23:59

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US3802074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:48

**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 ☐

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

02 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

06 FEB 2022 23:59

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US3802074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:48

| TIMEPOINT   | DAY 530  |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Have you been exposed to someone with known SARS-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="checkbox"/><br>Yes <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="checkbox"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Please identify below 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="checkbox"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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09 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

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13 FEB 2022 23:59

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US3802074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:48

TIMEPOINT

DAY 537

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

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

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

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

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

Fever (Temperature  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐  
Chills ☐  
Cough ☐  
Shortness of breath ☐  
Difficulty breathing ☐  
Fatigue ☐  
Muscle aches ☐  
Body aches ☐  
Headache ☐  
New loss of taste ☐  
New loss of smell ☐  
Sore throat ☐  
Congestion ☐  
Runny nose ☐  
Nausea ☐  
Vomiting ☐  
Diarrhea ☐

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

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

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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16 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

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20 FEB 2022 23:59

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US3802074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:48

| 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="checkbox"/><br>Yes <input type="checkbox"/>  |
| Have you been exposed to someone with known SARS-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="checkbox"/><br>Yes <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="checkbox"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Please identify below 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="checkbox"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

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Date and time of submission

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| <a href="#">Patient Cloud Open Date &amp; Time</a> | 23 FEB 2022 00:01 |
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|---|-------------------|
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 27 FEB 2022 23:59 |
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US3802074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:48

**TIMEPOINT**

DAY 551

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

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

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

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

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

Fever (Temperature  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐  
Chills ☐  
Cough ☐  
Shortness of breath ☐  
Difficulty breathing ☐  
Fatigue ☐  
Muscle aches ☐  
Body aches ☐  
Headache ☐  
New loss of taste ☐  
New loss of smell ☐  
Sore throat ☐  
Congestion ☐  
Runny nose ☐  
Nausea ☐  
Vomiting ☐  
Diarrhea ☐

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

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

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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02 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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06 MAR 2022 23:59

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US3802074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:48

**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 ☐

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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09 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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13 MAR 2022 23:59

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US3802074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:48

**TIMEPOINT**

DAY 565

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

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

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

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

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

Fever (Temperature  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐  
Chills ☐  
Cough ☐  
Shortness of breath ☐  
Difficulty breathing ☐  
Fatigue ☐  
Muscle aches ☐  
Body aches ☐  
Headache ☐  
New loss of taste ☐  
New loss of smell ☐  
Sore throat ☐  
Congestion ☐  
Runny nose ☐  
Nausea ☐  
Vomiting ☐  
Diarrhea ☐

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

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

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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16 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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20 MAR 2022 23:59

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US3802074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:48

**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 ☐

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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23 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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27 MAR 2022 23:59

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US3802074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:48

**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 ☐

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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30 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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03 APR 2022 23:59

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US3802074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:48

| 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 <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Have you been exposed to someone with known SARS-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="checkbox"/><br>Yes <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="checkbox"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Please identify below 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="checkbox"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |

**US3802074**

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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 <input type="checkbox"/> |
|---|--|

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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06 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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10 APR 2022 23:59

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US3802074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:48

**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 ☐

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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13 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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17 APR 2022 23:59

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US3802074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:48

| 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="checkbox"/><br>Yes <input type="checkbox"/>  |
| Have you been exposed to someone with known SARS-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="checkbox"/><br>Yes <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="checkbox"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Please identify below 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="checkbox"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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20 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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24 APR 2022 23:59

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US3802074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:48

| 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="checkbox"/><br>Yes <input type="checkbox"/>  |
| Have you been exposed to someone with known SARS-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="checkbox"/><br>Yes <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="checkbox"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Please identify below 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="checkbox"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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27 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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01 MAY 2022 23:59

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US3802074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:48

| 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="checkbox"/><br>Yes <input type="checkbox"/>  |
| Have you been exposed to someone with known SARS-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="checkbox"/><br>Yes <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="checkbox"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Please identify below 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="checkbox"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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04 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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08 MAY 2022 23:59

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US3802074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:48

| 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="checkbox"/><br>Yes <input type="checkbox"/>  |
| Have you been exposed to someone with known SARS-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="checkbox"/><br>Yes <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="checkbox"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Please identify below 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="checkbox"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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11 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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15 MAY 2022 23:59

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US3802074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:48

**TIMEPOINT**

DAY 628

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

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

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

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

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

Fever (Temperature  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐  
Chills ☐  
Cough ☐  
Shortness of breath ☐  
Difficulty breathing ☐  
Fatigue ☐  
Muscle aches ☐  
Body aches ☐  
Headache ☐  
New loss of taste ☐  
New loss of smell ☐  
Sore throat ☐  
Congestion ☐  
Runny nose ☐  
Nausea ☐  
Vomiting ☐  
Diarrhea ☐

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

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

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

22 MAY 2022 23:59

US3802074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:48

**TIMEPOINT**

DAY 635

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

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

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

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

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

Fever (Temperature  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐  
Chills ☐  
Cough ☐  
Shortness of breath ☐  
Difficulty breathing ☐  
Fatigue ☐  
Muscle aches ☐  
Body aches ☐  
Headache ☐  
New loss of taste ☐  
New loss of smell ☐  
Sore throat ☐  
Congestion ☐  
Runny nose ☐  
Nausea ☐  
Vomiting ☐  
Diarrhea ☐

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

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

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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25 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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29 MAY 2022 23:59

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US3802074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:48

| 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="checkbox"/><br>Yes <input type="checkbox"/>  |
| Have you been exposed to someone with known SARS-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="checkbox"/><br>Yes <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="checkbox"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Please identify below 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="checkbox"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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01 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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05 JUN 2022 23:59

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US3802074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:48

**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 ☐  
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 ☐

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

12 JUN 2022 23:59



US3802074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:48

**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 ☐  
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 ☐

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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15 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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19 JUN 2022 23:59

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US3802074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:48

**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 ☐

**US3802074**

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

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**Generated On: 10 Jun 2021 09:55:48**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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22 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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26 JUN 2022 23:59

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US3802074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:48

| 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="checkbox"/><br>Yes <input type="checkbox"/>  |
| Have you been exposed to someone with known SARS-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="checkbox"/><br>Yes <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="checkbox"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Please identify below 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="checkbox"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |

**US3802074**

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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 <input type="checkbox"/> |
|---|--|

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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29 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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03 JUL 2022 23:59

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US3802074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:48

**TIMEPOINT**

DAY 677

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

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

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

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

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

Fever (Temperature  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐  
Chills ☐  
Cough ☐  
Shortness of breath ☐  
Difficulty breathing ☐  
Fatigue ☐  
Muscle aches ☐  
Body aches ☐  
Headache ☐  
New loss of taste ☐  
New loss of smell ☐  
Sore throat ☐  
Congestion ☐  
Runny nose ☐  
Nausea ☐  
Vomiting ☐  
Diarrhea ☐

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

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

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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06 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

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10 JUL 2022 23:59

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US3802074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:48

| 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="checkbox"/><br>Yes <input type="checkbox"/>  |
| Have you been exposed to someone with known SARS-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="checkbox"/><br>Yes <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="checkbox"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Please identify below 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="checkbox"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

17 JUL 2022 23:59

US3802074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:48

| 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="checkbox"/><br>Yes <input type="checkbox"/>  |
| Have you been exposed to someone with known SARS-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="checkbox"/><br>Yes <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="checkbox"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Please identify below 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="checkbox"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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20 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

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24 JUL 2022 23:59

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US3802074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:48

**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 ☐

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

31 JUL 2022 23:59

US3802074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:48

**TIMEPOINT**

DAY 705

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

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

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

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

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

Fever (Temperature  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐  
Chills ☐  
Cough ☐  
Shortness of breath ☐  
Difficulty breathing ☐  
Fatigue ☐  
Muscle aches ☐  
Body aches ☐  
Headache ☐  
New loss of taste ☐  
New loss of smell ☐  
Sore throat ☐  
Congestion ☐  
Runny nose ☐  
Nausea ☐  
Vomiting ☐  
Diarrhea ☐

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

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

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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03 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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07 AUG 2022 23:59

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US3802074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:48

| 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="checkbox"/><br>Yes <input type="checkbox"/>  |
| Have you been exposed to someone with known SARS-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="checkbox"/><br>Yes <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="checkbox"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Please identify below 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="checkbox"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

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Date and time of submission

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|  |                   |
|--|-------------------|
| <a href="#">Patient Cloud Open Date &amp; Time</a> | 10 AUG 2022 00:01 |
|--|-------------------|

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|   |                   |
|---|-------------------|
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 14 AUG 2022 23:59 |
|---|-------------------|

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US3802074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:48

**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 ☐  
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 ☐

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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17 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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21 AUG 2022 23:59

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US3802074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:48

| 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="checkbox"/><br>Yes <input type="checkbox"/>  |
| Have you been exposed to someone with known SARS-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="checkbox"/><br>Yes <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="checkbox"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Please identify below 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="checkbox"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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24 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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28 AUG 2022 23:59

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US3802074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:48

| 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="checkbox"/><br>Yes <input type="checkbox"/>  |
| Have you been exposed to someone with known SARS-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="checkbox"/><br>Yes <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="checkbox"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Please identify below 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="checkbox"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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31 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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04 SEP 2022 23:59

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US3802074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:48

| 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="checkbox"/><br>Yes <input type="checkbox"/>  |
| Have you been exposed to someone with known SARS-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="checkbox"/><br>Yes <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="checkbox"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Please identify below 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="checkbox"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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07 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

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11 SEP 2022 23:59

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US3802074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:48

| 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="checkbox"/><br>Yes <input type="checkbox"/>  |
| Have you been exposed to someone with known SARS-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="checkbox"/><br>Yes <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="checkbox"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Please identify below 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="checkbox"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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14 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

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18 SEP 2022 23:59

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US3802074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:48

| 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"/>   |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

|   |                   |
|---|-------------------|
| Date and time of submission                         |                   |
| <a href="#">Patient Cloud Open Date &amp; Time</a>  | 21 SEP 2022 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 25 SEP 2022 23:59 |

US3802074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:48

| 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="checkbox"/><br>Yes <input type="checkbox"/>  |
| Have you been exposed to someone with known SARS-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="checkbox"/><br>Yes <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="checkbox"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Please identify below 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="checkbox"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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28 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

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02 OCT 2022 23:59

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US3802074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:48

**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 ☐  
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 ☐

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

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Date and time of submission

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|  |                   |
|--|-------------------|
| <a href="#">Patient Cloud Open Date &amp; Time</a> | 05 OCT 2022 00:01 |
|--|-------------------|

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|   |                   |
|---|-------------------|
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 09 OCT 2022 23:59 |
|---|-------------------|

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US3802074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:48

**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 ☐  
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 ☐

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

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Date and time of submission

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|  |                   |
|--|-------------------|
| <a href="#">Patient Cloud Open Date &amp; Time</a> | 12 OCT 2022 00:01 |
|--|-------------------|

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|   |                   |
|---|-------------------|
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 16 OCT 2022 23:59 |
|---|-------------------|

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US3802074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:48

**TIMEPOINT**

DAY 782

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

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

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

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

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

Fever (Temperature  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐  
Chills ☐  
Cough ☐  
Shortness of breath ☐  
Difficulty breathing ☐  
Fatigue ☐  
Muscle aches ☐  
Body aches ☐  
Headache ☐  
New loss of taste ☐  
New loss of smell ☐  
Sore throat ☐  
Congestion ☐  
Runny nose ☐  
Nausea ☐  
Vomiting ☐  
Diarrhea ☐

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

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

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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19 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

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23 OCT 2022 23:59

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US3802074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:48

**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 ☐  
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 ☐

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

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Date and time of submission

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|  |                   |
|--|-------------------|
| <a href="#">Patient Cloud Open Date &amp; Time</a> | 26 OCT 2022 00:01 |
|--|-------------------|

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|   |                   |
|---|-------------------|
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 30 OCT 2022 23:59 |
|---|-------------------|

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US3802074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:48

| 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="checkbox"/><br>Yes <input type="checkbox"/>  |
| Have you been exposed to someone with known SARS-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="checkbox"/><br>Yes <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="checkbox"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Please identify below 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="checkbox"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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02 NOV 2022 00:01

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[Patient Cloud Close Date & Time](#)

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06 NOV 2022 23:59

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US3802074

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary

Generated On: 10 Jun 2021 09:55:48

| Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other? | Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache? | Date & Time of Submission |
|---|--|---------------------------|
| No  |  | 07 MAR 2021 12:20:20      |

US3802074

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 28 Jan 2021 18:19:30

Generated On: 10 Jun 2021 09:55:48

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3802074

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 28 Jan 2021 18:19:30

Generated On: 10 Jun 2021 09:55:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3802074

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 28 Jan 2021 18:19:30

Generated On: 10 Jun 2021 09:55:48

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

US3802074

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 28 Jan 2021 18:19:30

Generated On: 10 Jun 2021 09:55:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3802074

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 28 Jan 2021 18:19:30

Generated On: 10 Jun 2021 09:55:48

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3802074

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 28 Jan 2021 18:19:30

Generated On: 10 Jun 2021 09:55:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3802074

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 03 Mar 2021 16:29:49

Generated On: 10 Jun 2021 09:55:48

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

24 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3802074

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 03 Mar 2021 16:29:49

Generated On: 10 Jun 2021 09:55:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3802074

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 25 Mar 2021 17:58:59

Generated On: 10 Jun 2021 09:55:48

|   |   |
|---|---|
| Was this visit performed?                                       | Yes <input checked="" type="radio"/>    |
|   | No <input type="radio"/>                |
| Visit date (dd MMM yyyy)  | 25 MAR 2021                             |
| Was visit performed at the participant's home or at the clinic? | Home <input type="radio"/>              |
|   | Clinic <input checked="" type="radio"/> |
| Folder OID  | VISIT4                                  |

US3802074

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 31 Mar 2021 19:46:35

Generated On: 10 Jun 2021 09:55:48

Were vital signs assessed? Yes ☐  
No ☒

Date of assessment (dd MMM yyyy) \_\_\_\_\_

Time of assessment (00:00-23:59) \_\_\_\_\_

Vital Signs Date and Time (derived) \_\_\_\_\_

Temperature (xxx.x) \_\_\_\_\_

Route of measurement Oral ☐  
Axillary ☐  
Other ☐

If Other, specify \_\_\_\_\_

Pulse (xxx) \_\_\_\_\_

Pulse units \_\_\_\_\_

Respiratory Rate (xxx) \_\_\_\_\_

Respiratory Rate units \_\_\_\_\_

Systolic Blood Pressure (xxx) \_\_\_\_\_

Systolic Blood Pressure units \_\_\_\_\_

Diastolic Blood Pressure (xxx) \_\_\_\_\_

Diastolic Blood Pressure units \_\_\_\_\_

Height (derived) \_\_\_\_\_

Weight (derived) \_\_\_\_\_

US3802074

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 25 Mar 2021 17:58:59

Generated On: 10 Jun 2021 09:55:48

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.*

US3802074

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 25 Mar 2021 17:58:59

Generated On: 10 Jun 2021 09:55:48

|                           |                                      |
|---------------------------|--------------------------------------|
| Was the sample collected? | Yes <input checked="" type="radio"/> |
|                           | No <input type="radio"/>             |

|                               |             |
|-------------------------------|-------------|
| Collection date (dd MMM yyyy) | 25 MAR 2021 |
|-------------------------------|-------------|

|                               |               |
|-------------------------------|---------------|
| Collection time (00:00-23:59) | 09:25 (24 HR) |
|-------------------------------|---------------|

|                                    |                   |
|------------------------------------|-------------------|
| Collection date and time (derived) | 25 MAR 2021 09:25 |
|------------------------------------|-------------------|

US3802074

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 25 Mar 2021 17:58:59

Generated On: 10 Jun 2021 09:55:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3802074

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 26 Apr 2021 19:01:59

Generated On: 10 Jun 2021 09:55:48

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

26 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3802074

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 19:01:59

Generated On: 10 Jun 2021 09:55:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

**US3802074**

**Folder: Safety Call Day 269 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:55:48**

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*

**US3802074**

**Folder: Safety Call Day 269 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:55:48**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3802074

Folder: Covid-19 Assessment 06 Jan 2021

Form: COVID-19 Contact

Data signed: (b) (4) 30 Apr 2021 16:16:20

Generated On: 10 Jun 2021 09:55:48

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

US3802074

Folder: Covid-19 Assessment 06 Jan 2021

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 28 Jan 2021 18:19:30

Generated On: 10 Jun 2021 09:55:48

---

[Generate Next COVID-19 Assessment](#)

Yes ☐

No ☒

---

US3802074

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Data signed: (b) (4) 28 Jan 2021 18:19:30

Generated On: 10 Jun 2021 09:55:48

|                           |                                      |
|---------------------------|--------------------------------------|
| Was this visit performed? | Yes <input checked="" type="radio"/> |
|                           | No <input type="radio"/>             |

|                          |             |
|--------------------------|-------------|
| Visit date (dd MMM yyyy) | 13 JAN 2021 |
|--------------------------|-------------|

|   |   |
|---|---|
| Was visit performed at the participant's home or at the clinic? | Home <input type="radio"/>              |
|   | Clinic <input checked="" type="radio"/> |

|            |               |
|------------|---------------|
| Folder OID | UNBLND_DECIDE |
|------------|---------------|

US3802074

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Data signed: (b) (4) 08 Apr 2021 18:35:40

Generated On: 10 Jun 2021 09:55:48

Date of updated informed consent (*dd MMM yyyy*) 13 JAN 2021

N/A - Subject Unblinded under Amendment 5 and Discontinued from Study False

Was the participant unblinded? Yes ☒ No ☐

Under what version of the Protocol was the Participant unblinded? Amendment 5 ☐ Amendment 6 or later ☒

Date of unblinding (*dd MMM yyyy*) 13 JAN 2021

Participant randomization assignment mRNA-1273 ☒ Placebo ☐

Actual Dose 1 mRNA-1273 ☒ Placebo ☐ Not Administered ☐

Actual Dose 2 mRNA-1273 ☒ Placebo ☐ Not Administered ☐

Will participant receive mRNA-1273? Yes ☐ No ☒

Placebo Only Flag \_\_\_\_\_  
Continuing with mRNA-1273 \_\_\_\_\_



US3802074

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 28 Jan 2021 18:19:30

Generated On: 10 Jun 2021 09:55:48

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

13 JAN 2021

Collection time (00:00-23:59)

08:40 (24 HR)

Collection date and time (derived)

13 JAN 2021 08:40

US3802074

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 28 Jan 2021 18:19:30

Generated On: 10 Jun 2021 09:55:48

|                                    |                                      |
|------------------------------------|--------------------------------------|
| Was the sample collected?          | Yes <input checked="" type="radio"/> |
|                                    | No <input type="radio"/>             |
| Collection date (dd MMM yyyy)      | 13 JAN 2021                          |
| Collection time (00:00 - 23:59)    | 08:35                                |
| Collection Date and Time (derived) | 13 JAN 2021 08:35                    |

US3802074

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 31 Mar 2021 19:46:34

Generated On: 10 Jun 2021 09:55:48

---

Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

---

US3802074

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 19 Apr 2021 17:42:02

Generated On: 10 Jun 2021 09:55:48

|  |  |
|--|--|
| AEID   | USA-US098-2021-MRNA-1273-P30<br>1000003  |
| Adverse event  | ACUTE CHOLECYSTITIS  |
| 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)                                       | 27 MAR 2021  |
| 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)                         | 29 MAR 2021  |
| 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)                          | 27 MAR 2021  |
| Hospital Discharge Date (dd MMM yyyy)                          | 29 MAR 2021  |
| Admitted to ICU?   | Yes <input type="radio"/><br>No <input checked="" type="radio"/><br>Unknown <input type="radio"/>  |

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 19 Apr 2021 17:42:02

Generated On: 10 Jun 2021 09:55:48

|  |   |
|--|---|
| Number of Days in ICU  |   |
| 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 Withdrawn <input type="radio"/><br>Not Applicable <input checked="" type="radio"/>  |
| Other action taken (check all that apply)                                    |   |
| None   | False   |
| Concomitant Medication   | True  |
| Concomitant Procedure  | True  |
| Outcome  | Fatal <input type="radio"/><br>Not Recovered/Not Resolved <input type="radio"/><br>Recovered/Resolved <input 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 (1)

Data signed: (b) (4) 19 Apr 2021 17:42:02

Generated On: 10 Jun 2021 09:55:48

---

PARTICIPANT EXPERIENCED  
INCREASED ABDOMINAL PAIN  
ON 26/MAR/2021. HE WAS  
EVALUATED AT THE ED ON  
27/MAR/2021 AND ADMITTED  
FOR OBSERVATION. HE HAD  
SURGERY,  
CHOLECYSTECTOMY, ON  
28/MAR/2021. HE WAS  
DISCHARGED FROM HOSPITAL  
WITHOUT COMPLICATIONS ON  
29/MAR/2021. LABORATORY  
UNITS UNAVAILABLE.

---

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

---

US3802074

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 19 Apr 2021 17:42:02

Generated On: 10 Jun 2021 09:55:48

|  |  |
|--|--|
| AEID   |  |
| Adverse event  | WORSENING HYPERTENSION   |
| 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)                                       | 01 MAR 2021  |
| Start time (00:00-23:59)                                       |  |
| AE start date and time (derived)                               |  |
| Ongoing?   | Yes <input checked="" type="radio"/><br>No <input type="radio"/>   |
| If not Ongoing, end date (dd MMM yyyy)                         |  |
| End time (00:00-23:59)   |  |
| AE End Date and Time (derived)                                 |  |
| Severity   | Grade 1/Mild <input type="radio"/><br>Grade 2/Moderate <input checked="" type="radio"/><br>Grade 3/Severe <input type="radio"/><br>Grade 4 <input type="radio"/> |
| Is the adverse event serious?                                  | Yes <input type="radio"/><br>No <input checked="" type="radio"/>   |
| AE is serious due To (check all that apply)                    |  |
| Death  | False  |
| Life threatening   | False  |
| Requires inpatient or prolongation of existing Hospitalization | False  |
| Hospital Admission Date (dd MMM yyyy)                          |  |
| Hospital Discharge Date (dd MMM yyyy)                          |  |
| Admitted to ICU?   | Yes <input type="radio"/><br>No <input type="radio"/><br>Unknown <input type="radio"/>   |
| Number of Days in ICU  |  |

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 19 Apr 2021 17:42:02

Generated On: 10 Jun 2021 09:55:48

|  |   |
|--|---|
| 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 type="radio"/><br>Recovered/Resolved with Sequelae <input type="radio"/><br>Recovering/Resolving <input checked="" type="radio"/><br>Unknown <input type="radio"/> |
| If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: |   |
| Narrative  |   |
| Serious Adverse Event Derived (CSA Programming Field Only)                   | 0   |
| Medically Attended AE Derived (CSA Programming Field Only)                   | 1   |
| Admitted to ICU Derived (CSA Programming Field Only)                         |   |



US3802074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 28 Jan 2021 18:19:30

Generated On: 10 Jun 2021 09:55:48

---

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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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 08 Apr 2021 18:35:40

Generated On: 10 Jun 2021 09:55:48

Name of Medication ATENOLOL

Prophylaxis Yes ☐  
No ☒

Indication HYPERTENSION

Dose per administration 50

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☒  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 08 Apr 2021 18:35:40

Generated On: 10 Jun 2021 09:55:48

|  |                          |                                  |
|--|--------------------------|----------------------------------|
|  | 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"/>         |
| If route of administration is Other, specify _____ |                          |                                  |
| Start date (dd MMM yyyy)                           | UN UNK 2005              |                                  |
| 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 (2)

Data signed: (b) (4) 08 Apr 2021 18:35:40

Generated On: 10 Jun 2021 09:55:48

Name of Medication SIMVASTATIN

Prophylaxis Yes ☐  
No ☒

Indication HIGH CHOLESTEROL

Dose per administration 20

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☒  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 08 Apr 2021 18:35:40

Generated On: 10 Jun 2021 09:55:48

|  |                          |                                  |
|--|--------------------------|----------------------------------|
|  | 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"/>         |
| If route of administration is Other, specify _____ |                          |                                  |
| Start date (dd MMM yyyy)                           | UN UNK 2005              |                                  |
| 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)

Data signed: (b) (4) 08 Apr 2021 18:35:40

Generated On: 10 Jun 2021 09:55:48

Name of Medication SUDAFED (PSEUDOEPHEDRINE HCL)

Prophylaxis Yes ☐  
No ☒

Indication SEASONAL ALLERGIES

Dose per administration UNKNOWN

Dose unit mg ☐  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☒

If dose unit is Other, specify UNKNOWN

Frequency once daily ☐  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☒  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 08 Apr 2021 18:35:40

Generated On: 10 Jun 2021 09:55:48

|  |                          |                                  |
|--|--------------------------|----------------------------------|
|  | Intraocular              | <input type="checkbox"/>         |
|  | 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"/>         |
| If route of administration is Other, specify _____ |                          |                                  |
| Start date (dd MMM yyyy) _____                     |                          |                                  |
| Start date completely unknown                      |                          | True                             |
| 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) _____             |                          |                                  |
| Interval Dosage Unit Number (derived) _____        |                          |                                  |
| 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 (4)

Data signed: (b) (4) 08 Apr 2021 18:35:40

Generated On: 10 Jun 2021 09:55:48

Name of Medication ADVIL

Prophylaxis Yes ☐  
No ☒

Indication PAIN AT INJECTION SITE

Dose per administration 400

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☐  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☒  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 08 Apr 2021 18:35:40

Generated On: 10 Jun 2021 09:55:48

|  |                          |                                     |
|--|--------------------------|-------------------------------------|
|  | 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"/>            |
| If route of administration is Other, specify _____ |                          |                                     |
| Start date (dd MMM yyyy)                           |                          | 1 SEP 2020                          |
| Start date completely unknown                      |                          | False                               |
| Ongoing?   | Yes                      | <input type="checkbox"/>            |
|  | No                       | <input checked="" type="checkbox"/> |
| If not Ongoing, End date (dd MMM yyyy)             |                          | 06 SEP 2020                         |
| Was this medication taken for solicited event?     | Yes                      | <input checked="" type="checkbox"/> |
|  | No                       | <input type="checkbox"/>            |
| Separate Dosage Number (derived) _____             |                          |                                     |
| Interval Dosage Unit Number (derived) _____        |                          |                                     |
| Interval Dosage Definition (derived)               | 802                      | <input type="checkbox"/>            |
|  | 803                      | <input type="checkbox"/>            |
|  | 804                      | <input type="checkbox"/>            |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 08 Apr 2021 18:35:40

Generated On: 10 Jun 2021 09:55:48

Name of Medication CLARITIN

Prophylaxis Yes ☐  
No ☒

Indication SINUS HEADACHE RELATED TO  
SEASONAL ALLERGIES

Dose per administration UNK

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☐  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☒  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 08 Apr 2021 18:35:40

Generated On: 10 Jun 2021 09:55:48

|  |                          |                                     |
|--|--------------------------|-------------------------------------|
|  | Intraocular              | <input type="checkbox"/>            |
|  | 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"/>            |
| If route of administration is Other, specify _____ |                          |                                     |
| Start date (dd MMM yyyy)                           | 1 SEP 2020               |                                     |
| Start date completely unknown                      | False                    |                                     |
| Ongoing?   | Yes                      | <input type="checkbox"/>            |
|  | No                       | <input checked="" type="checkbox"/> |
| If not Ongoing, End date (dd MMM yyyy)             |                          | 6 SEP 2020                          |
| Was this medication taken for solicited event?     | Yes                      | <input type="checkbox"/>            |
|  | No                       | <input checked="" type="checkbox"/> |
| Separate Dosage Number (derived) _____             |                          |                                     |
| Interval Dosage Unit Number (derived) _____        |                          |                                     |
| Interval Dosage Definition (derived)               | 802                      | <input type="checkbox"/>            |
|  | 803                      | <input type="checkbox"/>            |
|  | 804                      | <input type="checkbox"/>            |

US3802074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 08 Apr 2021 18:35:40

Generated On: 10 Jun 2021 09:55:48

Name of Medication ADVIL

Prophylaxis Yes ☐  
No ☒

Indication ARM PAIN AT INJECTION SITE  
HEADACHE

Dose per administration 400

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☐  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☒  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3802074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 08 Apr 2021 18:35:40

Generated On: 10 Jun 2021 09:55:48

|  |                          |                                     |
|--|--------------------------|-------------------------------------|
|  | Intraocular              | <input type="checkbox"/>            |
|  | 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"/>            |
| If route of administration is Other, specify _____ |                          |                                     |
| Start date (dd MMM yyyy)                           |                          | 29 SEP 2020                         |
| Start date completely unknown                      |                          | False                               |
| Ongoing?   | Yes                      | <input type="checkbox"/>            |
|  | No                       | <input checked="" type="checkbox"/> |
| If not Ongoing, End date (dd MMM yyyy)             |                          | 1 OCT 2020                          |
| Was this medication taken for solicited event?     | Yes                      | <input checked="" type="checkbox"/> |
|  | No                       | <input type="checkbox"/>            |
| Separate Dosage Number (derived) _____             |                          |                                     |
| Interval Dosage Unit Number (derived) _____        |                          |                                     |
| Interval Dosage Definition (derived)               | 802                      | <input type="checkbox"/>            |
|  | 803                      | <input type="checkbox"/>            |
|  | 804                      | <input type="checkbox"/>            |

US3802074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 08 Apr 2021 18:35:40

Generated On: 10 Jun 2021 09:55:48

Name of Medication LOSARTAN HCTZ

Prophylaxis Yes ☐  
No ☒

Indication HYPERTENSION

Dose per administration 50-12.5

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☒  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3802074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 08 Apr 2021 18:35:40

Generated On: 10 Jun 2021 09:55:48

|  |                          |                                  |
|--|--------------------------|----------------------------------|
|  | 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"/>         |
| If route of administration is Other, specify _____ |                          |                                  |
| Start date (dd MMM yyyy)                           | 1 MAR 2021               |                                  |
| 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"/> |

US3802074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 08 Apr 2021 18:35:40

Generated On: 10 Jun 2021 09:55:48

Name of Medication CIPROFLOXACIN

Prophylaxis Yes ☐  
No ☒

Indication PRESCRIBED FOR PARTICIPANT  
UPON DISCHARGE FROM  
HOSPITAL AFTER  
CHOLECYSTECTOMY  
SURGERY.

Dose per administration 500

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☐  
twice daily ☒  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 08 Apr 2021 18:35:40

Generated On: 10 Jun 2021 09:55:48

|  |                          |                                     |
|--|--------------------------|-------------------------------------|
|  | Subcutaneous             | <input type="checkbox"/>            |
|  | Transdermal              | <input type="checkbox"/>            |
|  | Intraocular              | <input type="checkbox"/>            |
|  | 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"/>            |
| If route of administration is Other, specify _____ |                          |                                     |
| Start date (dd MMM yyyy)                           | 29 MAR 2021              |                                     |
| Start date completely unknown                      | False                    |                                     |
| Ongoing?   | Yes                      | <input type="checkbox"/>            |
|  | No                       | <input checked="" type="checkbox"/> |
| If not Ongoing, End date (dd MMM yyyy)             | 05 APR 2021              |                                     |
| Was this medication taken for solicited event?     | Yes                      | <input type="checkbox"/>            |
|  | No                       | <input checked="" type="checkbox"/> |
| Separate Dosage Number (derived)                   | 2                        |                                     |
| Interval Dosage Unit Number (derived)              | 1                        |                                     |
| Interval Dosage Definition (derived)               | 802                      | <input type="checkbox"/>            |
|  | 803                      | <input type="checkbox"/>            |
|  | 804                      | <input checked="" type="checkbox"/> |

US3802074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 08 Apr 2021 18:35:40

Generated On: 10 Jun 2021 09:55:48

Name of Medication OXYCODONE

Prophylaxis Yes ☐  
No ☒

Indication POST OPERATIVE PAIN

Dose per administration 5

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☐  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☒  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

PRODUCTION RELEASE (v12.003  
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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 08 Apr 2021 18:35:40

Generated On: 10 Jun 2021 09:55:48

|  |                          |                                     |
|--|--------------------------|-------------------------------------|
|  | 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"/>            |
| If route of administration is Other, specify _____ |                          |                                     |
| Start date (dd MMM yyyy)                           | 29 MAR 2021              |                                     |
| Start date completely unknown                      | False                    |                                     |
| Ongoing?   | Yes                      | <input type="checkbox"/>            |
|  | No                       | <input checked="" type="checkbox"/> |
| If not Ongoing, End date (dd MMM yyyy)             |                          | 01 APR 2021                         |
| Was this medication taken for solicited event?     | Yes                      | <input type="checkbox"/>            |
|  | No                       | <input checked="" type="checkbox"/> |
| Separate Dosage Number (derived) _____             |                          |                                     |
| Interval Dosage Unit Number (derived) _____        |                          |                                     |
| Interval Dosage Definition (derived)               | 802                      | <input type="checkbox"/>            |
|  | 803                      | <input type="checkbox"/>            |
|  | 804                      | <input type="checkbox"/>            |

US3802074

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 31 Mar 2021 19:46:35

Generated On: 10 Jun 2021 09:55:48

---

Were any concomitant procedures performed?

Yes ☒

No ☐

---

If yes, please complete Concomitant Procedures form.

---

US3802074

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 31 Mar 2021 19:46:35

Generated On: 10 Jun 2021 09:55:48

| Procedure/Surgery date (dd MMM<br>yyyy) | Procedure/Surgery | Indication | If indication is Other, specify |
|---|-------------------|------------|---------------------------------|
| 28 MAR 2021                             | CHOLECYSTECTOMY   | Other      | INCREASED ABDOMINAL PAIN        |

US3802074

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 09:55:48

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

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 09:55:48

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 ☐

US3802074

Folder: SAE USA-US098-2021-MRNA-1273-P301000003

Form: Safety Report Form

Data signed: (b) (4) 20 Apr 2021 15:11:04

Generated On: 10 Jun 2021 09:55:48

|  |  |
|--|--|
| SAEID  | USA-US098-2021-MRNA-1273-P301000003                              |
| Serious  | Yes <input checked="" type="radio"/><br>No <input type="radio"/> |
| Death  | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Life threatening   | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Requires inpatient or prolongation of existing Hospitalization | Yes <input 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                                      | JUDITH   |
| Investigator's Last Name                                       | MARTIN   |
| Site Address: Street   | 3420 FIFTH AVE   |
| Site Address: City   | PITTSBURGH   |
| Site Address: State  | PA   |
| Site Address: Postal Code                                      | 15213  |
| Investigator Country   | US   |
| E2B Transmit Flag (Derived/Hidden)                             | 4  |



US3802074

Folder: SAE USA-US098-2021-MRNA-1273-P301000003

Form: Safety Report Form (1)

Data signed: (b) (4) 20 Apr 2021 15:11:04

Generated On: 10 Jun 2021 09:55:48

|   |  |
|---|--|
| SAEID   | USA-US098-2021-MRNA-1273-P301000003                              |
| Serious   | Yes <input checked="" type="radio"/><br>No <input type="radio"/> |
| Death   | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Life threatening  | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Requires inpatient or prolongation of existing Hospitalization  | Yes <input 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   | JUDITH   |
| Investigator's Last Name  | MARTIN   |
| Site Address: Street  | 3420 FIFTH AVE   |
| Site Address: City  | PITTSBURGH   |
| Site Address: State   | PA   |
| Site Address: Postal Code   | 15213  |
| Investigator Country  | US   |
| E2B Transmit Flag (Derived/Hidden)  | 4  |
| Date of submission (Pre-filled from custom function)  | 01/APR/2021 11:47  |
| 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   |

US3802074

Folder: SAE USA-US098-2021-MRNA-1273-P301000003

Form: Safety Report Form (2)

Data signed: (b) (4) 20 Apr 2021 15:11:04

Generated On: 10 Jun 2021 09:55:48

|   |  |
|---|--|
| SAEID   | USA-US098-2021-MRNA-1273-P301000003                              |
| Serious   | Yes <input checked="" type="radio"/><br>No <input type="radio"/> |
| Death   | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Life threatening  | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Requires inpatient or prolongation of existing Hospitalization  | Yes <input 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   | JUDITH   |
| Investigator's Last Name  | MARTIN   |
| Site Address: Street  | 3420 FIFTH AVE   |
| Site Address: City  | PITTSBURGH   |
| Site Address: State   | PA   |
| Site Address: Postal Code   | 15213  |
| Investigator Country  | US   |
| E2B Transmit Flag (Derived/Hidden)  | 4  |
| Date of submission (Pre-filled from custom function)  | 06/APR/2021 07:41  |
| Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge. | True   |

US3802074

Folder: SAE USA-US098-2021-MRNA-1273-P301000003

Form: Safety Report Form (3)

Data signed: (b) (4) 20 Apr 2021 15:11:04

Generated On: 10 Jun 2021 09:55:48

|   |  |
|---|--|
| SAEID   | USA-US098-2021-MRNA-1273-P301000003                              |
| Serious   | Yes <input checked="" type="radio"/><br>No <input type="radio"/> |
| Death   | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Life threatening  | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Requires inpatient or prolongation of existing Hospitalization  | Yes <input 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   | JUDITH   |
| Investigator's Last Name  | MARTIN   |
| Site Address: Street  | 3420 FIFTH AVE   |
| Site Address: City  | PITTSBURGH   |
| Site Address: State   | PA   |
| Site Address: Postal Code   | 15213  |
| Investigator Country  | US   |
| E2B Transmit Flag (Derived/Hidden)  | 4  |
| Date of submission (Pre-filled from custom function)  | 08/APR/2021 06:18  |
| 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   |

US3802074

Folder: SAE USA-US098-2021-MRNA-1273-P301000003

Form: Safety Report Form (4)

Data signed: (b) (4) 20 Apr 2021 15:11:04

Generated On: 10 Jun 2021 09:55:48

|   |  |
|---|--|
| SAEID   | USA-US098-2021-MRNA-1273-P301000003                              |
| Serious   | Yes <input checked="" type="radio"/><br>No <input type="radio"/> |
| Death   | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Life threatening  | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Requires inpatient or prolongation of existing Hospitalization  | Yes <input 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   | JUDITH   |
| Investigator's Last Name  | MARTIN   |
| Site Address: Street  | 3420 FIFTH AVE   |
| Site Address: City  | PITTSBURGH   |
| Site Address: State   | PA   |
| Site Address: Postal Code   | 15213  |
| Investigator Country  | US   |
| E2B Transmit Flag (Derived/Hidden)  | 4  |
| Date of submission (Pre-filled from custom function)  | 19/APR/2021 17:16  |
| 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

US3802074 (Prod: UPMC University Center)

**US3802074**

**Form: Participant Creation**

**Generated On: 10 Jun 2021 09:55:48**

[Participant ID](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)      | 15 Apr 2021 14:38:10 |
|                           |                       |                      |
| User signature succeeded. | Judith Martin (b) (4) | 28 Jan 2021 18:19:31 |
|                           | (b) (4)               |                      |
| User entered 'US3802074'  | RWS_ENDPOINT          | 31 Aug 2020 13:09:34 |
|                           | ENDPOINT (b) (4)      |                      |
|                           |                       |                      |

US3802074

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:55:48

[Was this visit performed?](#)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 28 Apr 2021 11:19:23 |
| User signature succeeded. | Judith Martin (b) (4)            | 28 Jan 2021 18:19:31 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)      | 17 Sep 2020 13:12:11 |
| User entered 'Yes (Y)'    | Lalicia Roman (b) (4)<br>(b) (4) | 31 Aug 2020 13:10:13 |

US3802074

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:55:48

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

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                 | 28 Apr 2021 11:19:23 |
| User signature succeeded.  | Judith Martin (b) (4)            | 28 Jan 2021 18:19:31 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6)      | 17 Sep 2020 13:12:11 |
| User entered '31 AUG 2020' | RWS_ENDPOINT<br>ENDPOINT (b) (4) | 31 Aug 2020 13:09:35 |



US3802074

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:55:48

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

| Audit                          | User                             | Time (GMT)           |
|--------------------------------|----------------------------------|----------------------|
| Data hard locked.              | (b) (4), (b) (6)                 | 28 Apr 2021 11:19:23 |
| User signature succeeded.      | Judith Martin (b) (4)            | 28 Jan 2021 18:19:31 |
| DataPoint Verified.            | (b) (4)<br>(b) (4), (b) (6)      | 17 Sep 2020 13:12:11 |
| User entered 'Clinic (Clinic)' | Lalicia Roman (b) (4)<br>(b) (4) | 31 Aug 2020 13:10:13 |

**US3802074**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:55:48**

[Folder OID](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 11:19:23 |
| User entered 'SCRN' | System           | 31 Aug 2020 13:10:13 |

US3802074

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:55:48

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

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                 | 28 Apr 2021 11:19:23 |
| User signature succeeded.  | Judith Martin (b) (4)            | 28 Jan 2021 18:19:31 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6)      | 17 Sep 2020 13:12:58 |
| User entered (b) (6) 1950' | RWS_ENDPOINT<br>ENDPOINT (b) (4) | 31 Aug 2020 13:09:36 |

**US3802074**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:55:48**

[Age](#)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 28 Apr 2021 11:19:23 |
| User signature succeeded. | Judith Martin (b) (4)            | 28 Jan 2021 18:19:31 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)      | 17 Sep 2020 13:12:58 |
| User entered '69'         | Lalicia Roman (b) (4)<br>(b) (4) | 31 Aug 2020 13:10:45 |

**US3802074**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:55:48**

[Age Units](#)

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 28 Apr 2021 11:19:23 |
| User entered 'YEARS' | System           | 31 Aug 2020 13:10:45 |

**US3802074**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:55:48**

[Age \(Derived\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 11:19:23 |
| User entered '69' | System           | 31 Aug 2020 13:11:01 |

**US3802074**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:55:48**

[Sex](#)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 28 Apr 2021 11:19:23 |
| User signature succeeded. | Judith Martin (b) (4)            | 28 Jan 2021 18:19:31 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)      | 17 Sep 2020 13:12:58 |
| User entered 'Male (M)'   | Lalicia Roman (b) (4)<br>(b) (4) | 31 Aug 2020 13:10:45 |

**US3802074**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:55:48**

[Ethnicity](#)

| Audit  | User                             | Time (GMT)           |
|--|----------------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)                 | 28 Apr 2021 11:19:23 |
| User signature succeeded.                                      | Judith Martin (b) (4)            | 28 Jan 2021 18:19:31 |
| DataPoint Verified.  | (b) (4)<br>(b) (4), (b) (6)      | 17 Sep 2020 13:12:58 |
| User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)' | Lalicia Roman (b) (4)<br>(b) (4) | 31 Aug 2020 13:10:45 |



**US3802074**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:55:48**

**White**

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 28 Apr 2021 11:19:23 |
| User signature succeeded. | Judith Martin (b) (4)            | 28 Jan 2021 18:19:31 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)      | 17 Sep 2020 13:12:58 |
| User entered 'l'          | Lalicia Roman (b) (4)<br>(b) (4) | 31 Aug 2020 13:10:45 |

US3802074

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:55:48

[Black](#)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 28 Apr 2021 11:19:23 |
| User signature succeeded. | Judith Martin (b) (4)            | 28 Jan 2021 18:19:31 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)      | 17 Sep 2020 13:12:58 |
| User entered '0'          | Lalicia Roman (b) (4)<br>(b) (4) | 31 Aug 2020 13:10:45 |

**US3802074**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:55:48**

[Asian](#)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 28 Apr 2021 11:19:23 |
| User signature succeeded. | Judith Martin (b) (4)            | 28 Jan 2021 18:19:31 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)      | 17 Sep 2020 13:12:58 |
| User entered '0'          | Lalicia Roman (b) (4)<br>(b) (4) | 31 Aug 2020 13:10:45 |

**US3802074**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:55:48**

[American Indian or Alaska Native](#)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 28 Apr 2021 11:19:23 |
| User signature succeeded. | Judith Martin (b) (4)            | 28 Jan 2021 18:19:31 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)      | 17 Sep 2020 13:12:58 |
| User entered '0'          | Lalicia Roman (b) (4)<br>(b) (4) | 31 Aug 2020 13:10:45 |

**US3802074**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:55:48**

[Native Hawaiian or other Pacific Islander](#)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 28 Apr 2021 11:19:23 |
| User signature succeeded. | Judith Martin (b) (4)            | 28 Jan 2021 18:19:31 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)      | 17 Sep 2020 13:12:58 |
| User entered '0'          | Lalicia Roman (b) (4)<br>(b) (4) | 31 Aug 2020 13:10:45 |

**US3802074**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:55:48**

[Other](#)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 28 Apr 2021 11:19:23 |
| User signature succeeded. | Judith Martin (b) (4)            | 28 Jan 2021 18:19:31 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)      | 17 Sep 2020 13:12:58 |
| User entered '0'          | Lalicia Roman (b) (4)<br>(b) (4) | 31 Aug 2020 13:10:45 |

**US3802074**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:55:48**

[If race is Other, specify](#)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 28 Apr 2021 11:19:23 |
| User signature succeeded. | Judith Martin (b) (4)            | 28 Jan 2021 18:19:31 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)      | 17 Sep 2020 13:12:58 |
| User entered empty.       | Lalicia Roman (b) (4)<br>(b) (4) | 31 Aug 2020 13:10:45 |

**US3802074**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:55:48**

[Unknown](#)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 28 Apr 2021 11:19:23 |
| User signature succeeded. | Judith Martin (b) (4)            | 28 Jan 2021 18:19:31 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)      | 17 Sep 2020 13:12:58 |
| User entered '0'          | Lalicia Roman (b) (4)<br>(b) (4) | 31 Aug 2020 13:10:45 |



**US3802074**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:55:48**

[Not reported](#)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 28 Apr 2021 11:19:23 |
| User signature succeeded. | Judith Martin (b) (4)            | 28 Jan 2021 18:19:31 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)      | 17 Sep 2020 13:12:58 |
| User entered '0'          | Lalicia Roman (b) (4)<br>(b) (4) | 31 Aug 2020 13:10:45 |

US3802074

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:55:48

Date of Informed Consent (*dd MMM yyyy*)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                 | 28 Apr 2021 11:19:23 |
| User signature succeeded.  | Judith Martin (b) (4)            | 28 Jan 2021 18:19:31 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6)      | 17 Sep 2020 13:13:14 |
| User entered '31 Aug 2020' | Lalicia Roman (b) (4)<br>(b) (4) | 31 Aug 2020 13:11:01 |

**US3802074**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:55:48**

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

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| Data hard locked.       | (b) (4), (b) (6) | 28 Apr 2021 11:19:23 |
| User entered 'Aug 2020' | System           | 31 Aug 2020 13:11:01 |

**US3802074**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:55:48**

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 11:19:23 |
| User entered '2020' | System           | 31 Aug 2020 13:11:01 |

**US3802074**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:55:48**

[Protocol Version](#)

| Audit                          | User                             | Time (GMT)           |
|--------------------------------|----------------------------------|----------------------|
| Data hard locked.              | (b) (4), (b) (6)                 | 28 Apr 2021 11:19:23 |
| User signature succeeded.      | Judith Martin (b) (4)            | 28 Jan 2021 18:19:31 |
| DataPoint Verified.            | (b) (4)<br>(b) (4), (b) (6)      | 17 Sep 2020 13:13:14 |
| User entered 'Amendment 3 (3)' | Lalicia Roman (b) (4)<br>(b) (4) | 31 Aug 2020 13:11:01 |

US3802074

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:55:48

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

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 28 Apr 2021 11:19:23 |
| User signature succeeded. | Judith Martin (b) (4)            | 28 Jan 2021 18:19:31 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)      | 17 Sep 2020 13:13:14 |
| User entered 'Yes (Y)'    | Lalicia Roman (b) (4)<br>(b) (4) | 31 Aug 2020 13:11:01 |

**US3802074**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:55:48**

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

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 28 Apr 2021 11:19:23 |
| User signature succeeded. | Judith Martin (b) (4)            | 28 Jan 2021 18:19:31 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)      | 17 Sep 2020 13:13:14 |
| User entered empty.       | Lalicia Roman (b) (4)<br>(b) (4) | 31 Aug 2020 13:11:01 |

US3802074

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:55:48

If reason for screen fail is Other, specify

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 28 Apr 2021 11:19:23 |
| User signature succeeded. | Judith Martin (b) (4)            | 28 Jan 2021 18:19:31 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)      | 17 Sep 2020 13:13:14 |
| User entered empty.       | Lalicia Roman (b) (4)<br>(b) (4) | 31 Aug 2020 13:11:01 |



US3802074

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:55:48

[Was this participant screened previously?](#)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 28 Apr 2021 11:19:23 |
| User signature succeeded. | Judith Martin (b) (4)            | 28 Jan 2021 18:19:31 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)      | 17 Sep 2020 13:13:14 |
| User entered 'No (N)'     | Lalicia Roman (b) (4)<br>(b) (4) | 31 Aug 2020 13:11:01 |

US3802074

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:55:48

[If Yes, previous participant number](#)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 28 Apr 2021 11:19:23 |
| User signature succeeded. | Judith Martin (b) (4)            | 28 Jan 2021 18:19:31 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)      | 17 Sep 2020 13:13:14 |
| User entered empty.       | RWS_ENDPOINT<br>ENDPOINT (b) (4) | 31 Aug 2020 13:09:35 |

**US3802074**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:55:48**

[Enrollment Trigger](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 11:19:23 |
| User entered 'I'  | System           | 31 Aug 2020 13:11:51 |

**US3802074**

**Folder: Screening**

**Form: Inclusion/Exclusion Criteria Summary**

**Generated On: 10 Jun 2021 09:55:48**

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

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 28 Apr 2021 11:19:23 |
| User signature succeeded. | Judith Martin (b) (4)            | 28 Jan 2021 18:19:31 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)      | 17 Sep 2020 13:13:39 |
| User entered 'Yes (Y)'    | Lalicia Roman (b) (4)<br>(b) (4) | 31 Aug 2020 13:11:51 |

US3802074

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 09:55:48

[Were any significant conditions reported?](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 28 Apr 2021 11:19:23 |
| User signature succeeded. | Judith Martin (b) (4)             | 28 Jan 2021 18:19:31 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 17 Sep 2020 13:13:46 |
| User entered 'Yes (Y)'    | Dominic Kramer (b) (4)<br>(b) (4) | 31 Aug 2020 13:46:12 |

US3802074

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:55:48

Condition

| Audit   | User                              | Time (GMT)           |
|---|-----------------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)                  | 28 Apr 2021 11:19:23 |
| User signature succeeded.   | Judith Martin (b) (4)             | 28 Jan 2021 18:19:31 |
| DataPoint Verified.   | (b) (4)<br>(b) (4), (b) (6)       | 17 Sep 2020 13:14:23 |
| User coded data point as SOC: Immune system disorders, HLG: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0. | Coder Import (b) (4)<br>(b) (4)   | 31 Aug 2020 13:48:52 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.  | Coder Import (b) (4)<br>(b) (4)   | 31 Aug 2020 13:48:52 |
| Data point term sent to Coder   | System                            | 31 Aug 2020 13:47:47 |
| User entered 'Seasonal Allergies'   | Dominic Kramer (b) (4)<br>(b) (4) | 31 Aug 2020 13:47:04 |

**US3802074**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:55:48**

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

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 28 Apr 2021 11:19:23 |
| User signature succeeded. | Judith Martin (b) (4)             | 28 Jan 2021 18:19:31 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 17 Sep 2020 13:14:25 |
| User entered empty.       | Dominic Kramer (b) (4)<br>(b) (4) | 31 Aug 2020 13:47:04 |

**US3802074**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:55:48**

[Start date completely unknown](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 28 Apr 2021 11:19:23 |
| User signature succeeded. | Judith Martin (b) (4)             | 28 Jan 2021 18:19:31 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 17 Sep 2020 13:14:29 |
| User entered 'I'          | Dominic Kramer (b) (4)<br>(b) (4) | 31 Aug 2020 13:47:04 |



**US3802074**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:55:48**

[Condition ongoing at study entry](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 28 Apr 2021 11:19:23 |
| User signature succeeded. | Judith Martin (b) (4)             | 28 Jan 2021 18:19:31 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 17 Sep 2020 13:14:31 |
| User entered 'Yes (Y)'    | Dominic Kramer (b) (4)<br>(b) (4) | 31 Aug 2020 13:47:04 |

**US3802074**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:55:48**

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

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 28 Apr 2021 11:19:23 |
| User signature succeeded. | Judith Martin (b) (4)             | 28 Jan 2021 18:19:31 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 17 Sep 2020 13:14:35 |
| User entered empty.       | Dominic Kramer (b) (4)<br>(b) (4) | 31 Aug 2020 13:47:04 |

**US3802074**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:55:48**

[Stop date completely unknown](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 28 Apr 2021 11:19:23 |
| User signature succeeded. | Judith Martin (b) (4)             | 28 Jan 2021 18:19:31 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 17 Sep 2020 13:14:39 |
| User entered '0'          | Dominic Kramer (b) (4)<br>(b) (4) | 31 Aug 2020 13:47:04 |

**US3802074**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:55:48**

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 11:19:23 |
| User entered empty. | System           | 31 Aug 2020 13:47:04 |

**US3802074**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:55:48**

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 11:19:23 |
| User entered empty. | System           | 31 Aug 2020 13:47:04 |

**US3802074**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:55:48**

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 11:19:23 |
| User entered empty. | System           | 31 Aug 2020 13:47:04 |

**US3802074**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:55:48**

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 11:19:23 |
| User entered empty. | System           | 31 Aug 2020 13:47:04 |

US3802074

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:55:48

[Condition](#)

| Audit  | User                              | Time (GMT)           |
|--|-----------------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)                  | 28 Apr 2021 11:19:23 |
| User signature succeeded.  | Judith Martin (b) (4)             | 28 Jan 2021 18:19:31 |
| DataPoint Verified.  | (b) (4)<br>(b) (4), (b) (6)       | 17 Sep 2020 13:15:07 |
| User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0. | Coder Import (b) (4)<br>(b) (4)   | 31 Aug 2020 13:49:52 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.   | Coder Import (b) (4)<br>(b) (4)   | 31 Aug 2020 13:49:52 |
| Data point term sent to Coder  | System                            | 31 Aug 2020 13:48:48 |
| User entered 'Hypertension'  | Dominic Kramer (b) (4)<br>(b) (4) | 31 Aug 2020 13:47:52 |



US3802074

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:55:48

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

| Audit                      | User                              | Time (GMT)           |
|----------------------------|-----------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                  | 28 Apr 2021 11:19:23 |
| User signature succeeded.  | Judith Martin (b) (4)             | 28 Jan 2021 18:19:31 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6)       | 17 Sep 2020 13:15:09 |
| User entered 'UN UNK 1990' | Dominic Kramer (b) (4)<br>(b) (4) | 31 Aug 2020 13:47:52 |

**US3802074**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:55:48**

[Start date completely unknown](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 28 Apr 2021 11:19:23 |
| User signature succeeded. | Judith Martin (b) (4)             | 28 Jan 2021 18:19:31 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 17 Sep 2020 13:15:11 |
| User entered '0'          | Dominic Kramer (b) (4)<br>(b) (4) | 31 Aug 2020 13:47:52 |

US3802074

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:55:48

[Condition ongoing at study entry](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 28 Apr 2021 11:19:23 |
| User signature succeeded. | Judith Martin (b) (4)             | 28 Jan 2021 18:19:31 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 17 Sep 2020 13:15:15 |
| User entered 'Yes (Y)'    | Dominic Kramer (b) (4)<br>(b) (4) | 31 Aug 2020 13:47:52 |

US3802074

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:55:48

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

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 28 Apr 2021 11:19:23 |
| User signature succeeded. | Judith Martin (b) (4)             | 28 Jan 2021 18:19:31 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 17 Sep 2020 13:15:24 |
| User entered empty.       | Dominic Kramer (b) (4)<br>(b) (4) | 31 Aug 2020 13:47:52 |

**US3802074**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:55:48**

[Stop date completely unknown](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 28 Apr 2021 11:19:23 |
| User signature succeeded. | Judith Martin (b) (4)             | 28 Jan 2021 18:19:31 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 17 Sep 2020 13:15:30 |
| User entered '0'          | Dominic Kramer (b) (4)<br>(b) (4) | 31 Aug 2020 13:47:52 |

**US3802074**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:55:48**

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

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| Data hard locked.       | (b) (4), (b) (6) | 28 Apr 2021 11:19:23 |
| User entered 'Jan 1990' | System           | 31 Aug 2020 13:47:52 |

**US3802074**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:55:48**

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 11:19:23 |
| User entered '1990' | System           | 31 Aug 2020 13:47:52 |

**US3802074**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:55:48**

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 11:19:23 |
| User entered empty. | System           | 31 Aug 2020 13:47:52 |



**US3802074**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:55:48**

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 11:19:23 |
| User entered empty. | System           | 31 Aug 2020 13:47:52 |

US3802074

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:55:48

Condition

| Audit  | User                              | Time (GMT)           |
|--|-----------------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)                  | 28 Apr 2021 11:19:23 |
| User signature succeeded.  | Judith Martin (b) (4)             | 28 Jan 2021 18:19:31 |
| DataPoint Verified.  | (b) (4)<br>(b) (4), (b) (6)       | 17 Sep 2020 13:16:51 |
| User coded data point as SOC: Investigations,<br>HLGT: Lipid analyses, HLT: Cholesterol analyses,<br>PT: Blood cholesterol increased, LLT: High<br>cholesterol - version MedDRA\\23.0. | Coder Import (b) (4)<br>(b) (4)   | 31 Aug 2020 13:50:50 |
| User coded data point as Term Coded data point by<br>User: Coder System - version MedDRA\\23.0.  | Coder Import (b) (4)<br>(b) (4)   | 31 Aug 2020 13:50:50 |
| Data point term sent to Coder  | System                            | 31 Aug 2020 13:49:50 |
| User entered 'High Cholesterol'  | Dominic Kramer (b) (4)<br>(b) (4) | 31 Aug 2020 13:49:05 |

**US3802074**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:55:48**

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

| Audit                      | User                              | Time (GMT)           |
|----------------------------|-----------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                  | 28 Apr 2021 11:19:23 |
| User signature succeeded.  | Judith Martin (b) (4)             | 28 Jan 2021 18:19:31 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6)       | 17 Sep 2020 13:16:51 |
| User entered 'UN UNK 1990' | Dominic Kramer (b) (4)<br>(b) (4) | 31 Aug 2020 13:49:05 |

**US3802074**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:55:48**

[Start date completely unknown](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 28 Apr 2021 11:19:23 |
| User signature succeeded. | Judith Martin (b) (4)             | 28 Jan 2021 18:19:31 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 17 Sep 2020 13:16:51 |
| User entered '0'          | Dominic Kramer (b) (4)<br>(b) (4) | 31 Aug 2020 13:49:05 |

US3802074

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:55:48

[Condition ongoing at study entry](#)

| Audit  | User                   | Time (GMT)           |
|--|------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)       | 28 Apr 2021 11:19:23 |
| User signature succeeded.  | Judith Martin (b) (4)  | 28 Jan 2021 18:19:31 |
| User closed query 'Source does not state ongoing at enrollment. please confirm. ' (Site from CRA).   | (b) (4)                |                      |
| Query 'Source does not state ongoing at enrollment. please confirm. ' answered with 'It is ongoing at enrollment. Simvastatin is still currently taken daily to treat the high cholesterol. ' (Site from CRA). | (b) (4), (b) (6)       | 17 Nov 2020 14:51:44 |
| DataPoint Verified.  | Emily Carney (b) (4)   | 20 Oct 2020 20:19:22 |
|  | (b) (4)                |                      |
|  | (b) (4), (b) (6)       | 17 Sep 2020 13:16:51 |
| User opened query 'Source does not state ongoing at enrollment. please confirm. ' (Site from CRA).   |                        | 17 Sep 2020 13:16:47 |
| User entered 'Yes (Y)'   | Dominic Kramer (b) (4) | 31 Aug 2020 13:49:05 |
|  | (b) (4)                |                      |

**US3802074**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:55:48**

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

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 28 Apr 2021 11:19:23 |
| User signature succeeded. | Judith Martin (b) (4)             | 28 Jan 2021 18:19:31 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 17 Sep 2020 13:16:51 |
| User entered empty.       | Dominic Kramer (b) (4)<br>(b) (4) | 31 Aug 2020 13:49:05 |

**US3802074**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:55:48**

[Stop date completely unknown](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 28 Apr 2021 11:19:23 |
| User signature succeeded. | Judith Martin (b) (4)             | 28 Jan 2021 18:19:31 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 17 Sep 2020 13:16:51 |
| User entered '0'          | Dominic Kramer (b) (4)<br>(b) (4) | 31 Aug 2020 13:49:05 |

**US3802074**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:55:48**

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

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| Data hard locked.       | (b) (4), (b) (6) | 28 Apr 2021 11:19:23 |
| User entered 'Jan 1990' | System           | 31 Aug 2020 13:49:05 |



**US3802074**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:55:48**

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 11:19:23 |
| User entered '1990' | System           | 31 Aug 2020 13:49:05 |

**US3802074**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:55:48**

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 11:19:23 |
| User entered empty. | System           | 31 Aug 2020 13:49:05 |

**US3802074**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:55:48**

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 11:19:23 |
| User entered empty. | System           | 31 Aug 2020 13:49:05 |

US3802074

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:55:48

[Were vital signs assessed?](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 28 Apr 2021 11:19:23 |
| User signature succeeded. | Judith Martin (b) (4)             | 28 Jan 2021 18:19:31 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 17 Sep 2020 13:18:49 |
| User entered 'Yes (Y)'    | Dominic Kramer (b) (4)<br>(b) (4) | 31 Aug 2020 13:50:25 |

US3802074

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:55:48

Date of assessment (*dd MMM yyyy*)

| Audit                      | User                              | Time (GMT)           |
|----------------------------|-----------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                  | 28 Apr 2021 11:19:23 |
| User signature succeeded.  | Judith Martin (b) (4)             | 28 Jan 2021 18:19:31 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6)       | 17 Sep 2020 13:18:49 |
| User entered '31 Aug 2020' | Dominic Kramer (b) (4)<br>(b) (4) | 31 Aug 2020 13:50:25 |

**US3802074**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:55:48**

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

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 28 Apr 2021 11:19:23 |
| User signature succeeded. | Judith Martin (b) (4)             | 28 Jan 2021 18:19:31 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 17 Sep 2020 13:18:49 |
| User entered '09:08'      | Dominic Kramer (b) (4)<br>(b) (4) | 31 Aug 2020 13:50:25 |

**US3802074**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:55:48**

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

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 28 Apr 2021 11:19:23 |
| User entered '31 Aug 2020 09:08' | System           | 31 Aug 2020 13:50:25 |

US3802074

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:55:48

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

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 11:19:23 |
| User signature succeeded. | Judith Martin (b) (4)       | 28 Jan 2021 18:19:31 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 17 Sep 2020 13:18:49 |
| User entered '181' cm     | Dominic Kramer (b) (4)      | 31 Aug 2020 13:50:25 |
| DataPoint set to visible. | (b) (4)<br>System           | 31 Aug 2020 13:11:51 |



US3802074

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:55:48

Weight (xxx.x)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 11:19:23 |
| User signature succeeded. | Judith Martin (b) (4)       | 28 Jan 2021 18:19:31 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 17 Sep 2020 13:18:49 |
| User entered '218' lb     | Dominic Kramer (b) (4)      | 31 Aug 2020 13:50:25 |
| DataPoint set to visible. | (b) (4)<br>System           | 31 Aug 2020 13:11:51 |

**US3802074**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:55:48**

**BMI (xxx.x)**

| Audit                     | User             | Time (GMT)           |
|---------------------------|------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6) | 28 Apr 2021 11:19:23 |
| User entered '30.24661'   | System           | 31 Aug 2020 13:50:25 |
| DataPoint set to visible. | System           | 31 Aug 2020 13:11:51 |

**US3802074**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:55:48**

[BMI units](#)

| Audit                     | User             | Time (GMT)           |
|---------------------------|------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6) | 28 Apr 2021 11:19:23 |
| User entered 'kg/m2'      | System           | 31 Aug 2020 13:50:25 |
| DataPoint set to visible. | System           | 31 Aug 2020 13:11:51 |

US3802074

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:55:48

Temperature (xxx.x)

| Audit   | User                              | Time (GMT)           |
|---|-----------------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)                  | 28 Apr 2021 11:19:23 |
| DataPoint Verified.   | (b) (4), (b) (6)                  | 23 Apr 2021 13:59:02 |
| User signature succeeded.   | Judith Martin (b) (4)             | 28 Jan 2021 18:19:31 |
| User closed query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3 Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).                     | (b) (4)<br>(b) (4), (b) (6)       | 08 Oct 2020 15:01:06 |
| Query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS' (Site from System).            | Melissa Andrasko (b) (4)          | 06 Oct 2020 15:17:26 |
| DataPoint Un-verified.  | (b) (4), (b) (6)                  | 17 Sep 2020 13:18:53 |
| DataPoint Verified.   | (b) (4), (b) (6)                  | 17 Sep 2020 13:18:49 |
| Amendment Manager: User opened query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System). | System                            | 17 Sep 2020 00:11:28 |
| User entered '96.6' F   | Dominic Kramer (b) (4)<br>(b) (4) | 31 Aug 2020 13:50:25 |

**US3802074**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:55:48**

[Route of measurement](#)

| Audit                        | User                              | Time (GMT)           |
|------------------------------|-----------------------------------|----------------------|
| Data hard locked.            | (b) (4), (b) (6)                  | 28 Apr 2021 11:19:23 |
| User signature succeeded.    | Judith Martin (b) (4)             | 28 Jan 2021 18:19:31 |
| DataPoint Verified.          | (b) (4)<br>(b) (4), (b) (6)       | 17 Sep 2020 13:18:49 |
| User entered 'Other (Other)' | Dominic Kramer (b) (4)<br>(b) (4) | 31 Aug 2020 13:50:25 |

US3802074

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:55:48

[If Other, specify](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 28 Apr 2021 11:19:23 |
| User signature succeeded. | Judith Martin (b) (4)             | 28 Jan 2021 18:19:31 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 17 Sep 2020 13:18:49 |
| User entered 'Infrared'   | Dominic Kramer (b) (4)<br>(b) (4) | 31 Aug 2020 13:50:25 |

US3802074

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:55:48

[Pulse \(xxx\)](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 28 Apr 2021 11:19:23 |
| User signature succeeded. | Judith Martin (b) (4)             | 28 Jan 2021 18:19:31 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 17 Sep 2020 13:18:49 |
| User entered '65'         | Dominic Kramer (b) (4)<br>(b) (4) | 31 Aug 2020 13:50:25 |

**US3802074**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:55:48**

[Pulse units](#)

| Audit              | User             | Time (GMT)           |
|--------------------|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 28 Apr 2021 11:19:23 |
| User entered 'bpm' | System           | 31 Aug 2020 13:50:25 |



US3802074

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:55:48

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

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 28 Apr 2021 11:19:23 |
| User signature succeeded. | Judith Martin (b) (4)             | 28 Jan 2021 18:19:31 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 17 Sep 2020 13:18:49 |
| User entered '18'         | Dominic Kramer (b) (4)<br>(b) (4) | 31 Aug 2020 13:50:25 |

**US3802074**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:55:48**

[Respiratory Rate units](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6) | 28 Apr 2021 11:19:23 |
| User entered 'breaths/min' | System           | 31 Aug 2020 13:50:25 |

US3802074

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:55:48

Systolic Blood Pressure (xxx)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 28 Apr 2021 11:19:23 |
| User signature succeeded. | Judith Martin (b) (4)             | 28 Jan 2021 18:19:31 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 17 Sep 2020 13:18:49 |
| User entered '146'        | Dominic Kramer (b) (4)<br>(b) (4) | 31 Aug 2020 13:50:25 |

**US3802074**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:55:48**

[Systolic Blood Pressure units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 11:19:23 |
| User entered 'mmHg' | System           | 31 Aug 2020 13:50:25 |

US3802074

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:55:48

Diastolic Blood Pressure (xxx)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 28 Apr 2021 11:19:23 |
| User signature succeeded. | Judith Martin (b) (4)             | 28 Jan 2021 18:19:31 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 17 Sep 2020 13:18:49 |
| User entered '81'         | Dominic Kramer (b) (4)<br>(b) (4) | 31 Aug 2020 13:50:25 |

**US3802074**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:55:48**

[Diastolic Blood Pressure units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 11:19:23 |
| User entered 'mmHg' | System           | 31 Aug 2020 13:50:25 |

**US3802074**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:55:48**

[Height \(derived\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 11:19:23 |
|                   |                  |                      |

US3802074

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:55:48

Weight (derived)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 11:19:23 |
|                   |                  |                      |



US3802074

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 09:55:48

[Was the physical examination performed?](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 28 Apr 2021 11:19:23 |
| User signature succeeded. | Judith Martin (b) (4)             | 28 Jan 2021 18:19:31 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 17 Sep 2020 13:19:24 |
| User entered 'Yes (Y)'    | Dominic Kramer (b) (4)<br>(b) (4) | 31 Aug 2020 13:53:12 |

US3802074

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 09:55:48

Date of examination (dd MMM yyyy)

| Audit                      | User                              | Time (GMT)           |
|----------------------------|-----------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                  | 28 Apr 2021 11:19:23 |
| User signature succeeded.  | Judith Martin (b) (4)             | 28 Jan 2021 18:19:31 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6)       | 17 Sep 2020 13:19:24 |
| User entered '31 Aug 2020' | Dominic Kramer (b) (4)<br>(b) (4) | 31 Aug 2020 13:53:12 |

US3802074

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:55:48

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

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 28 Apr 2021 11:19:23 |
| User signature succeeded. | Judith Martin (b) (4)             | 28 Jan 2021 18:19:31 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 17 Sep 2020 13:21:12 |
| User entered 'No (N)'     | Dominic Kramer (b) (4)<br>(b) (4) | 31 Aug 2020 13:52:17 |

US3802074

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:55:48

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

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 28 Apr 2021 11:19:23 |
| User signature succeeded. | Judith Martin (b) (4)             | 28 Jan 2021 18:19:31 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 17 Sep 2020 13:21:12 |
| User entered 'No (N)'     | Dominic Kramer (b) (4)<br>(b) (4) | 31 Aug 2020 13:52:17 |

US3802074

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:55:48

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

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 28 Apr 2021 11:19:23 |
| User signature succeeded. | Judith Martin (b) (4)             | 28 Jan 2021 18:19:31 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 17 Sep 2020 13:21:12 |
| User entered 'No (N)'     | Dominic Kramer (b) (4)<br>(b) (4) | 31 Aug 2020 13:52:17 |

US3802074

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:55:48

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

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 28 Apr 2021 11:19:23 |
| User signature succeeded. | Judith Martin (b) (4)             | 28 Jan 2021 18:19:31 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 17 Sep 2020 13:21:12 |
| User entered 'No (N)'     | Dominic Kramer (b) (4)<br>(b) (4) | 31 Aug 2020 13:52:17 |

US3802074

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:55:48

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

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 28 Apr 2021 11:19:23 |
| User signature succeeded. | Judith Martin (b) (4)             | 28 Jan 2021 18:19:31 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 17 Sep 2020 13:21:12 |
| User entered 'No (N)'     | Dominic Kramer (b) (4)<br>(b) (4) | 31 Aug 2020 13:52:17 |

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:55:48

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

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 28 Apr 2021 11:19:23 |
| User signature succeeded. | Judith Martin (b) (4)             | 28 Jan 2021 18:19:31 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 17 Sep 2020 13:21:12 |
| User entered 'No (N)'     | Dominic Kramer (b) (4)<br>(b) (4) | 31 Aug 2020 13:52:17 |



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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:55:48

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

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 28 Apr 2021 11:19:23 |
| User signature succeeded. | Judith Martin (b) (4)             | 28 Jan 2021 18:19:31 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 17 Sep 2020 13:21:12 |
| User entered 'No (N)'     | Dominic Kramer (b) (4)<br>(b) (4) | 31 Aug 2020 13:52:17 |

US3802074

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:55:48

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

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 28 Apr 2021 11:19:23 |
| User signature succeeded. | Judith Martin (b) (4)             | 28 Jan 2021 18:19:31 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 17 Sep 2020 13:21:12 |
| User entered 'No (N)'     | Dominic Kramer (b) (4)<br>(b) (4) | 31 Aug 2020 13:52:17 |

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:55:48

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

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 28 Apr 2021 11:19:23 |
| User signature succeeded. | Judith Martin (b) (4)             | 28 Jan 2021 18:19:31 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 17 Sep 2020 13:21:12 |
| User entered 'No (N)'     | Dominic Kramer (b) (4)<br>(b) (4) | 31 Aug 2020 13:52:17 |

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:55:48

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

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 28 Apr 2021 11:19:23 |
| User signature succeeded. | Judith Martin (b) (4)             | 28 Jan 2021 18:19:31 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 17 Sep 2020 13:21:12 |
| User entered 'No (N)'     | Dominic Kramer (b) (4)<br>(b) (4) | 31 Aug 2020 13:52:17 |

US3802074

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:55:48

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

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 28 Apr 2021 11:19:23 |
| User signature succeeded. | Judith Martin (b) (4)             | 28 Jan 2021 18:19:31 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 17 Sep 2020 13:21:12 |
| User entered 'No (N)'     | Dominic Kramer (b) (4)<br>(b) (4) | 31 Aug 2020 13:52:17 |

US3802074

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:55:48

[Other](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 28 Apr 2021 11:19:23 |
| User signature succeeded. | Judith Martin (b) (4)             | 28 Jan 2021 18:19:31 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 17 Sep 2020 13:21:12 |
| User entered 'Yes (Y)'    | Dominic Kramer (b) (4)<br>(b) (4) | 31 Aug 2020 13:52:17 |

US3802074

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:55:48

[Specify](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 28 Apr 2021 11:19:23 |
| User signature succeeded. | Judith Martin (b) (4)             | 28 Jan 2021 18:19:31 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 17 Sep 2020 13:21:12 |
| User entered (b) (6)      | Dominic Kramer (b) (4)<br>(b) (4) | 31 Aug 2020 13:52:17 |

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:55:48

No Risk Identified

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 28 Apr 2021 11:19:23 |
| User signature succeeded. | Judith Martin (b) (4)<br>(b) (4)  | 28 Jan 2021 18:19:31 |
| User entered '0'          | Dominic Kramer (b) (4)<br>(b) (4) | 31 Aug 2020 13:52:17 |



US3802074

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:55:48

Resides in Nursing Home or Assisted Living Facility

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 28 Apr 2021 11:19:23 |
| User signature succeeded. | Judith Martin (b) (4)             | 28 Jan 2021 18:19:31 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 17 Sep 2020 13:21:12 |
| User entered '0'          | Dominic Kramer (b) (4)<br>(b) (4) | 31 Aug 2020 13:52:17 |

US3802074

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:55:48

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

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 28 Apr 2021 11:19:23 |
| User signature succeeded. | Judith Martin (b) (4)             | 28 Jan 2021 18:19:31 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 17 Sep 2020 13:21:12 |
| User entered '0'          | Dominic Kramer (b) (4)<br>(b) (4) | 31 Aug 2020 13:52:17 |

US3802074

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:55:48

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

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 28 Apr 2021 11:19:23 |
| User signature succeeded. | Judith Martin (b) (4)             | 28 Jan 2021 18:19:31 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 17 Sep 2020 13:21:12 |
| User entered '0'          | Dominic Kramer (b) (4)<br>(b) (4) | 31 Aug 2020 13:52:17 |

US3802074

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:55:48

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

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 28 Apr 2021 11:19:23 |
| User signature succeeded. | Judith Martin (b) (4)             | 28 Jan 2021 18:19:31 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 17 Sep 2020 13:21:12 |
| User entered '0'          | Dominic Kramer (b) (4)<br>(b) (4) | 31 Aug 2020 13:52:17 |

US3802074

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:55:48

[Resides in a single family home](#) (i.e., detached housing)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 28 Apr 2021 11:19:23 |
| User signature succeeded. | Judith Martin (b) (4)             | 28 Jan 2021 18:19:31 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 17 Sep 2020 13:21:12 |
| User entered 'I'          | Dominic Kramer (b) (4)<br>(b) (4) | 31 Aug 2020 13:52:17 |

US3802074

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:55:48

Other

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 28 Apr 2021 11:19:23 |
| User signature succeeded. | Judith Martin (b) (4)<br>(b) (4)  | 28 Jan 2021 18:19:31 |
| User entered '0'          | Dominic Kramer (b) (4)<br>(b) (4) | 31 Aug 2020 13:52:17 |

US3802074

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:55:48

[Specify](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 28 Apr 2021 11:19:23 |
| User signature succeeded. | Judith Martin (b) (4)             | 28 Jan 2021 18:19:31 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 17 Sep 2020 13:21:12 |
| User entered empty.       | Dominic Kramer (b) (4)<br>(b) (4) | 31 Aug 2020 13:52:17 |

**US3802074**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:55:48**

[Was this visit performed?](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 28 Apr 2021 11:19:23 |
| User signature succeeded. | Judith Martin (b) (4)             | 28 Jan 2021 18:19:31 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 17 Sep 2020 13:22:55 |
| User entered 'Yes (Y)'    | Dominic Kramer (b) (4)<br>(b) (4) | 31 Aug 2020 13:52:54 |



**US3802074**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:55:48**

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

| Audit                      | User                              | Time (GMT)           |
|----------------------------|-----------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                  | 28 Apr 2021 11:19:23 |
| User signature succeeded.  | Judith Martin (b) (4)             | 28 Jan 2021 18:19:31 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6)       | 17 Sep 2020 13:22:55 |
| User entered '31 Aug 2020' | Dominic Kramer (b) (4)<br>(b) (4) | 31 Aug 2020 13:52:54 |

US3802074

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:55:48

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

| Audit                          | User                              | Time (GMT)           |
|--------------------------------|-----------------------------------|----------------------|
| Data hard locked.              | (b) (4), (b) (6)                  | 28 Apr 2021 11:19:23 |
| User signature succeeded.      | Judith Martin (b) (4)             | 28 Jan 2021 18:19:31 |
| DataPoint Verified.            | (b) (4)<br>(b) (4), (b) (6)       | 17 Sep 2020 13:22:55 |
| User entered 'Clinic (Clinic)' | Dominic Kramer (b) (4)<br>(b) (4) | 31 Aug 2020 13:52:54 |

**US3802074**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:55:48**

[Folder OID](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| Data hard locked.     | (b) (4), (b) (6) | 28 Apr 2021 11:19:23 |
| User entered 'VISIT1' | System           | 31 Aug 2020 13:52:54 |

US3802074

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:55:48

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

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                 | 28 Apr 2021 11:19:23 |
| User signature succeeded.  | Judith Martin (b) (4)            | 28 Jan 2021 18:19:31 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6)      | 17 Sep 2020 13:23:49 |
| User entered '31 AUG 2020' | RWS_ENDPOINT<br>ENDPOINT (b) (4) | 31 Aug 2020 13:09:37 |

US3802074

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:55:48

What was the participant's randomization number?

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 28 Apr 2021 11:19:23 |
| User signature succeeded. | Judith Martin (b) (4)            | 28 Jan 2021 18:19:31 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)      | 17 Sep 2020 13:23:49 |
| User entered '188918'     | RWS_ENDPOINT<br>ENDPOINT (b) (4) | 31 Aug 2020 13:09:37 |

US3802074

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:55:48

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

| Audit                         | User                             | Time (GMT)           |
|-------------------------------|----------------------------------|----------------------|
| Data hard locked.             | (b) (4), (b) (6)                 | 28 Apr 2021 11:19:23 |
| User signature succeeded.     | Judith Martin (b) (4)            | 28 Jan 2021 18:19:31 |
| DataPoint Verified.           | (b) (4)<br>(b) (4), (b) (6)      | 17 Sep 2020 13:23:49 |
| User entered '>=65 years (3)' | RWS_ENDPOINT<br>ENDPOINT (b) (4) | 31 Aug 2020 13:09:37 |

US3802074

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:55:48

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

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 28 Apr 2021 11:19:23 |
| User signature succeeded. | Judith Martin (b) (4)            | 28 Jan 2021 18:19:31 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)      | 17 Sep 2020 13:23:49 |
| User entered 'No (N)'     | Lalicia Roman (b) (4)<br>(b) (4) | 31 Aug 2020 13:12:22 |

US3802074

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:55:48

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

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 28 Apr 2021 11:19:23 |
| User signature succeeded. | Judith Martin (b) (4)            | 28 Jan 2021 18:19:31 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)      | 17 Sep 2020 13:23:49 |
| User entered 'No (N)'     | Lalicia Roman (b) (4)<br>(b) (4) | 31 Aug 2020 13:12:22 |



US3802074

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:55:48

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

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 28 Apr 2021 11:19:23 |
| User signature succeeded. | Judith Martin (b) (4)            | 28 Jan 2021 18:19:31 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)      | 17 Sep 2020 13:23:49 |
| User entered 'No (N)'     | Lalicia Roman (b) (4)<br>(b) (4) | 31 Aug 2020 13:12:22 |

**US3802074**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 10 Jun 2021 09:55:48**

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

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 28 Apr 2021 11:19:23 |
| User signature succeeded. | Judith Martin (b) (4)            | 28 Jan 2021 18:19:31 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)      | 17 Sep 2020 13:23:49 |
| User entered 'No (N)'     | Lalicia Roman (b) (4)<br>(b) (4) | 31 Aug 2020 13:12:22 |

**US3802074**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 10 Jun 2021 09:55:48**

[Liver Disease](#)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 28 Apr 2021 11:19:23 |
| User signature succeeded. | Judith Martin (b) (4)            | 28 Jan 2021 18:19:31 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)      | 17 Sep 2020 13:23:49 |
| User entered 'No (N)'     | Lalicia Roman (b) (4)<br>(b) (4) | 31 Aug 2020 13:12:22 |

US3802074

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:55:48

Human Immunodeficiency Virus (HIV) infection

| Audit   | User                            | Time (GMT)           |
|---|---------------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)                | 28 Apr 2021 11:19:23 |
| DataPoint Verified.   | (b) (4), (b) (6)                | 23 Apr 2021 11:11:43 |
| User signature succeeded.   | Judith Martin (b) (4)           | 28 Jan 2021 18:19:31 |
| User closed query 'Per CDM: This field requires a Yes or No response. Please complete.' (Site from DM).   | (b) (4)<br>(b) (4), (b) (6)     | 08 Jan 2021 12:05:53 |
| Query 'Per CDM: This field requires a Yes or No response. Please complete.' answered with 'Per medical history this participant is HIV negative.' (Site from DM). | Emily Carney (b) (4)<br>(b) (4) | 07 Jan 2021 15:20:11 |
| User entered 'No (N)'   | Emily Carney (b) (4)<br>(b) (4) | 07 Jan 2021 15:20:06 |
| User opened query 'Per CDM: This field requires a Yes or No response. Please complete.' (Site from DM).   | (b) (4), (b) (6)                | 09 Dec 2020 18:08:58 |
| Amendment Manager: DataPoint set to visible.  | System                          | 19 Sep 2020 08:40:26 |
| Amendment Manager inserted this DataPoint.  | System                          | 19 Sep 2020 08:40:24 |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:55:48

Height

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 28 Apr 2021 11:19:23 |
| User signature succeeded. | Judith Martin (b) (4)            | 28 Jan 2021 18:19:31 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)      | 17 Sep 2020 13:24:56 |
| User entered '181' cm     | Lalicia Roman (b) (4)<br>(b) (4) | 31 Aug 2020 17:15:02 |

US3802074

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:55:48

Weight

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 28 Apr 2021 11:19:23 |
| User signature succeeded. | Judith Martin (b) (4)            | 28 Jan 2021 18:19:31 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)      | 17 Sep 2020 13:24:56 |
| User entered '218' lb     | Lalicia Roman (b) (4)<br>(b) (4) | 31 Aug 2020 17:15:02 |

US3802074

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:55:48

Height

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 28 Apr 2021 11:19:23 |
| User signature succeeded. | Judith Martin (b) (4)            | 28 Jan 2021 18:19:31 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)      | 17 Sep 2020 13:24:56 |
| User entered '181' cm     | Lalicia Roman (b) (4)<br>(b) (4) | 31 Aug 2020 17:15:02 |

US3802074

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:55:48

Weight

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 28 Apr 2021 11:19:23 |
| User signature succeeded. | Judith Martin (b) (4)            | 28 Jan 2021 18:19:31 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)      | 17 Sep 2020 13:24:56 |
| User entered '218' lb     | Lalicia Roman (b) (4)<br>(b) (4) | 31 Aug 2020 17:15:02 |



US3802074

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:55:48

[Timepoint](#)

| Audit  | User                             | Time (GMT)           |
|--|----------------------------------|----------------------|
| Data hard locked.                                | (b) (4), (b) (6)                 | 28 Apr 2021 11:19:23 |
| User accepted default value 'Pre-Dose (PREDOSE)' | Lalicia Roman (b) (4)<br>(b) (4) | 31 Aug 2020 17:15:02 |

US3802074

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:55:48

[Were vital signs assessed?](#)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 28 Apr 2021 11:19:23 |
| User signature succeeded. | Judith Martin (b) (4)            | 28 Jan 2021 18:19:31 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)      | 17 Sep 2020 13:24:53 |
| User entered 'Yes (Y)'    | Lalicia Roman (b) (4)<br>(b) (4) | 31 Aug 2020 17:15:02 |

US3802074

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:55:48

Date of assessment (*dd MMM yyyy*)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                 | 28 Apr 2021 11:19:23 |
| User signature succeeded.  | Judith Martin (b) (4)            | 28 Jan 2021 18:19:31 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6)      | 17 Sep 2020 13:24:56 |
| User entered '31 Aug 2020' | Lalicia Roman (b) (4)<br>(b) (4) | 31 Aug 2020 17:15:02 |

US3802074

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:55:48

Time of assessment (00:00-23:59)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 28 Apr 2021 11:19:23 |
| User signature succeeded. | Judith Martin (b) (4)            | 28 Jan 2021 18:19:31 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)      | 17 Sep 2020 13:24:56 |
| User entered '09:08'      | Lalicia Roman (b) (4)<br>(b) (4) | 31 Aug 2020 17:15:02 |

US3802074

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:55:48

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

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 28 Apr 2021 11:19:23 |
| User entered '31 Aug 2020 09:08' | System           | 31 Aug 2020 17:15:02 |

US3802074

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:55:48

Temperature (xxx.x)

| Audit   | User                             | Time (GMT)           |
|---|----------------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)                 | 28 Apr 2021 11:19:23 |
| DataPoint Verified.   |                                  | 23 Apr 2021 13:58:36 |
| User signature succeeded.   | Judith Martin (b) (4)            | 28 Jan 2021 18:19:31 |
| User closed query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3 Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).                     | (b) (4)<br>(b) (4), (b) (6)      | 08 Oct 2020 15:01:19 |
| Query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS' (Site from System).            | Melissa Andrasko (b) (4)         | 06 Oct 2020 15:17:53 |
| DataPoint Un-verified.  | (b) (4), (b) (6)                 | 17 Sep 2020 13:25:01 |
| DataPoint Verified.   |                                  | 17 Sep 2020 13:24:56 |
| Amendment Manager: User opened query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System). |                                  | 17 Sep 2020 00:11:28 |
| User entered '96.6' F   | Lalicia Roman (b) (4)<br>(b) (4) | 31 Aug 2020 17:15:02 |

US3802074

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:55:48

[Route of measurement](#)

| Audit                        | User                             | Time (GMT)           |
|------------------------------|----------------------------------|----------------------|
| Data hard locked.            | (b) (4), (b) (6)                 | 28 Apr 2021 11:19:23 |
| User signature succeeded.    | Judith Martin (b) (4)            | 28 Jan 2021 18:19:31 |
| DataPoint Verified.          | (b) (4)<br>(b) (4), (b) (6)      | 17 Sep 2020 13:24:56 |
| User entered 'Other (Other)' | Lalicia Roman (b) (4)<br>(b) (4) | 31 Aug 2020 17:15:02 |

US3802074

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:55:48

[If Other, specify](#)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 28 Apr 2021 11:19:23 |
| User signature succeeded. | Judith Martin (b) (4)            | 28 Jan 2021 18:19:31 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)      | 17 Sep 2020 13:24:56 |
| User entered 'infrared'   | Lalicia Roman (b) (4)<br>(b) (4) | 31 Aug 2020 17:15:02 |



US3802074

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:55:48

[Pulse \(xxx\)](#)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 28 Apr 2021 11:19:23 |
| User signature succeeded. | Judith Martin (b) (4)            | 28 Jan 2021 18:19:31 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)      | 17 Sep 2020 13:24:56 |
| User entered '65'         | Lalicia Roman (b) (4)<br>(b) (4) | 31 Aug 2020 17:15:02 |

**US3802074**

**Folder: Visit 1 Day 1**

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

**Generated On: 10 Jun 2021 09:55:48**

[Pulse units](#)

| Audit              | User             | Time (GMT)           |
|--------------------|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 28 Apr 2021 11:19:23 |
| User entered 'bpm' | System           | 31 Aug 2020 17:15:02 |

US3802074

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:55:48

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

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 28 Apr 2021 11:19:23 |
| User signature succeeded. | Judith Martin (b) (4)            | 28 Jan 2021 18:19:31 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)      | 17 Sep 2020 13:24:56 |
| User entered '18'         | Lalicia Roman (b) (4)<br>(b) (4) | 31 Aug 2020 17:15:02 |

US3802074

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:55:48

[Respiratory Rate units](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6) | 28 Apr 2021 11:19:23 |
| User entered 'breaths/min' | System           | 31 Aug 2020 17:15:02 |

US3802074

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:55:48

Systolic Blood Pressure (xxx)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 28 Apr 2021 11:19:23 |
| User signature succeeded. | Judith Martin (b) (4)            | 28 Jan 2021 18:19:31 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)      | 17 Sep 2020 13:24:56 |
| User entered '146'        | Lalicia Roman (b) (4)<br>(b) (4) | 31 Aug 2020 17:15:02 |

**US3802074**

**Folder: Visit 1 Day 1**

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

**Generated On: 10 Jun 2021 09:55:48**

[Systolic Blood Pressure units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 11:19:23 |
| User entered 'mmHg' | System           | 31 Aug 2020 17:15:02 |

US3802074

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:55:48

Diastolic Blood Pressure (xxx)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 28 Apr 2021 11:19:23 |
| User signature succeeded. | Judith Martin (b) (4)            | 28 Jan 2021 18:19:31 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)      | 17 Sep 2020 13:24:56 |
| User entered '81'         | Lalicia Roman (b) (4)<br>(b) (4) | 31 Aug 2020 17:15:02 |

US3802074

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:55:48

Diastolic Blood Pressure units

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 11:19:23 |
| User entered 'mmHg' | System           | 31 Aug 2020 17:15:02 |



US3802074

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:55:48

Height

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 28 Apr 2021 11:19:23 |
| User signature succeeded. | Judith Martin (b) (4)            | 28 Jan 2021 18:19:31 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)      | 17 Sep 2020 13:24:56 |
| User entered '181' cm     | Lalicia Roman (b) (4)<br>(b) (4) | 31 Aug 2020 17:15:02 |

US3802074

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:55:48

Weight

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 28 Apr 2021 11:19:23 |
| User signature succeeded. | Judith Martin (b) (4)            | 28 Jan 2021 18:19:31 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)      | 17 Sep 2020 13:24:56 |
| User entered '218' lb     | Lalicia Roman (b) (4)<br>(b) (4) | 31 Aug 2020 17:15:02 |

US3802074

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:55:48

[Timepoint](#)

| Audit  | User                             | Time (GMT)           |
|--|----------------------------------|----------------------|
| Data hard locked.                                  | (b) (4), (b) (6)                 | 28 Apr 2021 11:19:23 |
| User accepted default value 'Post-Dose (POSTDOSE)' | Lalicia Roman (b) (4)<br>(b) (4) | 31 Aug 2020 17:15:02 |

US3802074

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:55:48

[Were vital signs assessed?](#)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 28 Apr 2021 11:19:23 |
| User signature succeeded. | Judith Martin (b) (4)            | 28 Jan 2021 18:19:31 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)      | 17 Sep 2020 13:24:56 |
| User entered 'Yes (Y)'    | Lalicia Roman (b) (4)<br>(b) (4) | 31 Aug 2020 17:15:02 |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:55:48

Date of assessment (*dd MMM yyyy*)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                 | 28 Apr 2021 11:19:23 |
| User signature succeeded.  | Judith Martin (b) (4)            | 28 Jan 2021 18:19:31 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6)      | 17 Sep 2020 13:24:56 |
| User entered '31 Aug 2020' | Lalicia Roman (b) (4)<br>(b) (4) | 31 Aug 2020 17:15:02 |

US3802074

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:55:48

Time of assessment (00:00-23:59)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 28 Apr 2021 11:19:23 |
| User signature succeeded. | Judith Martin (b) (4)            | 28 Jan 2021 18:19:31 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)      | 17 Sep 2020 13:24:56 |
| User entered '10:19'      | Lalicia Roman (b) (4)<br>(b) (4) | 31 Aug 2020 17:15:02 |

US3802074

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:55:48

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

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 28 Apr 2021 11:19:23 |
| User entered '31 Aug 2020 10:19' | System           | 31 Aug 2020 17:15:02 |

US3802074

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:55:48

Temperature (xxx.x)

| Audit   | User                             | Time (GMT)           |
|---|----------------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)                 | 28 Apr 2021 11:19:23 |
| User signature succeeded.   | Judith Martin (b) (4)            | 28 Jan 2021 18:19:31 |
| User closed query "Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate." (Site from System).                    | (b) (4)<br>(b) (4), (b) (6)      | 08 Oct 2020 15:01:23 |
| Query "Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate." answered with 'NCS' (Site from System).            | Melissa Andrasko (b) (4)         | 06 Oct 2020 15:18:05 |
| DataPoint Verified.   | (b) (4), (b) (6)                 | 17 Sep 2020 13:24:56 |
| Amendment Manager: User opened query "Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate." (Site from System). | System                           | 17 Sep 2020 00:11:28 |
| User entered '96.7' F   | Lalicia Roman (b) (4)<br>(b) (4) | 31 Aug 2020 17:15:02 |



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:55:48

[Route of measurement](#)

| Audit                        | User                             | Time (GMT)           |
|------------------------------|----------------------------------|----------------------|
| Data hard locked.            | (b) (4), (b) (6)                 | 28 Apr 2021 11:19:23 |
| User signature succeeded.    | Judith Martin (b) (4)            | 28 Jan 2021 18:19:31 |
| DataPoint Verified.          | (b) (4)<br>(b) (4), (b) (6)      | 17 Sep 2020 13:24:56 |
| User entered 'Other (Other)' | Lalicia Roman (b) (4)<br>(b) (4) | 31 Aug 2020 17:15:02 |

US3802074

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:55:48

[If Other, specify](#)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 28 Apr 2021 11:19:23 |
| User signature succeeded. | Judith Martin (b) (4)            | 28 Jan 2021 18:19:31 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)      | 17 Sep 2020 13:24:56 |
| User entered 'infrared'   | Lalicia Roman (b) (4)<br>(b) (4) | 31 Aug 2020 17:15:02 |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:55:48

[Pulse \(xxx\)](#)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 28 Apr 2021 11:19:23 |
| User signature succeeded. | Judith Martin (b) (4)            | 28 Jan 2021 18:19:31 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)      | 17 Sep 2020 13:24:56 |
| User entered '62'         | Lalicia Roman (b) (4)<br>(b) (4) | 31 Aug 2020 17:15:02 |

**US3802074**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:55:48**

[Pulse units](#)

| Audit              | User             | Time (GMT)           |
|--------------------|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 28 Apr 2021 11:19:23 |
| User entered 'bpm' | System           | 31 Aug 2020 17:15:02 |

US3802074

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:55:48

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

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 28 Apr 2021 11:19:23 |
| User signature succeeded. | Judith Martin (b) (4)            | 28 Jan 2021 18:19:31 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)      | 17 Sep 2020 13:24:56 |
| User entered '20'         | Lalicia Roman (b) (4)<br>(b) (4) | 31 Aug 2020 17:15:02 |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:55:48

[Respiratory Rate units](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6) | 28 Apr 2021 11:19:23 |
| User entered 'breaths/min' | System           | 31 Aug 2020 17:15:02 |

US3802074

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:55:48

Systolic Blood Pressure (xxx)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 28 Apr 2021 11:19:23 |
| User signature succeeded. | Judith Martin (b) (4)            | 28 Jan 2021 18:19:31 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)      | 17 Sep 2020 13:24:56 |
| User entered '148'        | Lalicia Roman (b) (4)<br>(b) (4) | 31 Aug 2020 17:15:02 |

**US3802074**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:55:48**

[Systolic Blood Pressure units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 11:19:23 |
| User entered 'mmHg' | System           | 31 Aug 2020 17:15:02 |



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:55:48

Diastolic Blood Pressure (xxx)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 28 Apr 2021 11:19:23 |
| User signature succeeded. | Judith Martin (b) (4)            | 28 Jan 2021 18:19:31 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)      | 17 Sep 2020 13:24:56 |
| User entered '92'         | Lalicia Roman (b) (4)<br>(b) (4) | 31 Aug 2020 17:15:02 |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:55:48

Diastolic Blood Pressure units

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 11:19:23 |
| User entered 'mmHg' | System           | 31 Aug 2020 17:15:02 |

US3802074

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:55:48

[Was the physical examination performed?](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 28 Apr 2021 11:19:23 |
| User signature succeeded. | Judith Martin (b) (4)             | 28 Jan 2021 18:19:31 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 17 Sep 2020 13:26:25 |
| User entered 'Yes (Y)'    | Dominic Kramer (b) (4)<br>(b) (4) | 31 Aug 2020 13:53:28 |

**US3802074**

**Folder: Visit 1 Day 1**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:55:48**

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

| Audit                      | User                              | Time (GMT)           |
|----------------------------|-----------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                  | 28 Apr 2021 11:19:23 |
| User signature succeeded.  | Judith Martin (b) (4)             | 28 Jan 2021 18:19:31 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6)       | 17 Sep 2020 13:26:25 |
| User entered '31 Aug 2020' | Dominic Kramer (b) (4)<br>(b) (4) | 31 Aug 2020 13:53:28 |

US3802074

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:55:48

[Was study treatment given?](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 28 Apr 2021 11:19:23 |
| User signature succeeded. | Judith Martin (b) (4)             | 28 Jan 2021 18:19:31 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 17 Sep 2020 13:27:03 |
| User entered 'Yes (Y)'    | Dominic Kramer (b) (4)<br>(b) (4) | 31 Aug 2020 13:54:40 |

US3802074

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:55:48

[If No, reason not given](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 28 Apr 2021 11:19:23 |
| User signature succeeded. | Judith Martin (b) (4)             | 28 Jan 2021 18:19:31 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 17 Sep 2020 13:27:03 |
| User entered empty.       | Dominic Kramer (b) (4)<br>(b) (4) | 31 Aug 2020 13:54:40 |

US3802074

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:55:48

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

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 28 Apr 2021 11:19:23 |
| User signature succeeded. | Judith Martin (b) (4)             | 28 Jan 2021 18:19:31 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 17 Sep 2020 13:27:03 |
| User entered empty.       | Dominic Kramer (b) (4)<br>(b) (4) | 31 Aug 2020 13:54:40 |

**US3802074**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:55:48**

[What was the study treatment?](#)

| Audit                               | User             | Time (GMT)           |
|-------------------------------------|------------------|----------------------|
| Data hard locked.                   | (b) (4), (b) (6) | 28 Apr 2021 11:19:23 |
| User entered 'MRNA-1273 OR PLACEBO' | System           | 31 Aug 2020 13:54:40 |



US3802074

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:55:48

What was the treatment date? (dd MMM yyyy)

| Audit                      | User                              | Time (GMT)           |
|----------------------------|-----------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                  | 28 Apr 2021 11:19:23 |
| User signature succeeded.  | Judith Martin (b) (4)             | 28 Jan 2021 18:19:31 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6)       | 17 Sep 2020 13:27:03 |
| User entered '31 Aug 2020' | Dominic Kramer (b) (4)<br>(b) (4) | 31 Aug 2020 13:54:40 |

US3802074

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:55:48

[What was the treatment time? \(00:00-23:59\)](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 28 Apr 2021 11:19:23 |
| User signature succeeded. | Judith Martin (b) (4)             | 28 Jan 2021 18:19:31 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 17 Sep 2020 13:27:03 |
| User entered '09:45'      | Dominic Kramer (b) (4)<br>(b) (4) | 31 Aug 2020 13:54:40 |

**US3802074**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:55:48**

[Treatment Date and Time \(derived\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 28 Apr 2021 11:19:23 |
| User entered '31 Aug 2020 09:45' | System           | 31 Aug 2020 13:54:40 |

US3802074

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:55:48

[Which arm was used to give treatment?](#)

| Audit                              | User                              | Time (GMT)           |
|------------------------------------|-----------------------------------|----------------------|
| Data hard locked.                  | (b) (4), (b) (6)                  | 28 Apr 2021 11:19:23 |
| User signature succeeded.          | Judith Martin (b) (4)             | 28 Jan 2021 18:19:31 |
| DataPoint Verified.                | (b) (4)<br>(b) (4), (b) (6)       | 17 Sep 2020 13:27:03 |
| User entered 'Left Arm (LEFT ARM)' | Dominic Kramer (b) (4)<br>(b) (4) | 31 Aug 2020 13:54:40 |

US3802074

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:55:48

[What was the frequency of the study treatment dosing?](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 11:19:23 |
| DataPoint Verified. |                  | 17 Sep 2020 13:27:03 |
| User entered 'ONCE' | System           | 31 Aug 2020 13:54:40 |

**US3802074**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:55:48**

[What was the route of administration for the study treatment?](#)

| Audit                        | User             | Time (GMT)           |
|------------------------------|------------------|----------------------|
| Data hard locked.            | (b) (4), (b) (6) | 28 Apr 2021 11:19:23 |
| User entered 'INTRAMUSCULAR' | System           | 31 Aug 2020 13:54:40 |

US3802074

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:55:48

[Was the sample collected?](#)

| Audit                     | User   | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                             | 28 Apr 2021 11:19:23 |
| DataPoint Verified.       |  | 23 Apr 2021 20:54:56 |
| User signature succeeded. | Judith Martin (b) (4)                        | 28 Jan 2021 18:19:31 |
| User entered 'Yes (Y)'    | (b) (4)<br>Dominic Kramer (b) (4)<br>(b) (4) | 31 Aug 2020 13:55:09 |

US3802074

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:55:48

Collection date (dd MMM yyyy)

| Audit                      | User   | Time (GMT)           |
|----------------------------|--|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                             | 28 Apr 2021 11:19:23 |
| DataPoint Verified.        |  | 23 Apr 2021 20:54:56 |
| User signature succeeded.  | Judith Martin (b) (4)                        | 28 Jan 2021 18:19:31 |
| User entered '31 Aug 2020' | (b) (4)<br>Dominic Kramer (b) (4)<br>(b) (4) | 31 Aug 2020 13:55:09 |



**US3802074**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:55:48**

[Collection time \(00:00-23:59\)](#)

| Audit                     | User   | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                             | 28 Apr 2021 11:19:23 |
| DataPoint Verified.       |  | 23 Apr 2021 20:54:56 |
| User signature succeeded. | Judith Martin (b) (4)                        | 28 Jan 2021 18:19:31 |
| User entered '09:23'      | (b) (4)<br>Dominic Kramer (b) (4)<br>(b) (4) | 31 Aug 2020 13:55:09 |

**US3802074**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:55:48**

[Collection date and time \(derived\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 28 Apr 2021 11:19:23 |
| User entered '31 Aug 2020 09:23' | System           | 31 Aug 2020 13:55:09 |

**US3802074**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab**

**Generated On: 10 Jun 2021 09:55:48**

**Collection date** (*dd MMM yyyy*)

| Audit                      | User                              | Time (GMT)           |
|----------------------------|-----------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                  | 28 Apr 2021 11:19:23 |
| User signature succeeded.  | Judith Martin (b) (4)             | 28 Jan 2021 18:19:31 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6)       | 17 Sep 2020 13:27:59 |
| User entered '31 Aug 2020' | Dominic Kramer (b) (4)<br>(b) (4) | 31 Aug 2020 13:55:43 |

**US3802074**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:55:48**

[Lab Test](#)

| Audit  | User                              | Time (GMT)           |
|--|-----------------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)                  | 28 Apr 2021 11:19:23 |
| User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)' | Dominic Kramer (b) (4)<br>(b) (4) | 31 Aug 2020 13:55:43 |

US3802074

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:55:48

[Was the sample collected?](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 28 Apr 2021 11:19:23 |
| User signature succeeded. | Judith Martin (b) (4)             | 28 Jan 2021 18:19:31 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 17 Sep 2020 13:27:59 |
| User entered 'Yes (Y)'    | Dominic Kramer (b) (4)<br>(b) (4) | 31 Aug 2020 13:55:43 |

US3802074

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:55:48

Collection time (00:00 - 23:59)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 28 Apr 2021 11:19:23 |
| User signature succeeded. | Judith Martin (b) (4)             | 28 Jan 2021 18:19:31 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 17 Sep 2020 13:27:59 |
| User entered '09:28'      | Dominic Kramer (b) (4)<br>(b) (4) | 31 Aug 2020 13:55:43 |

**US3802074**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:55:48**

[Collection date and time \(derived\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 28 Apr 2021 11:19:23 |
| User entered '31 Aug 2020 09:28' | System           | 31 Aug 2020 13:55:43 |

**US3802074**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:55:48**

[Lab Test](#)

| Audit  | User                              | Time (GMT)           |
|--|-----------------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)                  | 28 Apr 2021 11:19:23 |
| User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)' | Dominic Kramer (b) (4)<br>(b) (4) | 31 Aug 2020 13:55:43 |



**US3802074**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:55:48**

[Was the sample collected?](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 28 Apr 2021 11:19:23 |
| User signature succeeded. | Judith Martin (b) (4)             | 28 Jan 2021 18:19:31 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 17 Sep 2020 13:27:59 |
| User entered 'No (N)'     | Dominic Kramer (b) (4)<br>(b) (4) | 31 Aug 2020 13:55:43 |

US3802074

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:55:48

Collection time (00:00 - 23:59)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 28 Apr 2021 11:19:23 |
| User signature succeeded. | Judith Martin (b) (4)             | 28 Jan 2021 18:19:31 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 17 Sep 2020 13:27:59 |
| User entered empty.       | Dominic Kramer (b) (4)<br>(b) (4) | 31 Aug 2020 13:55:43 |

**US3802074**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:55:48**

[Collection date and time \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 11:19:23 |
| User entered empty. | System           | 31 Aug 2020 13:55:43 |

US3802074

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 09:55:48

[Is the participant continuing to the next visit?](#)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                | 28 Apr 2021 11:19:23 |
| User signature succeeded. | Judith Martin (b) (4)           | 28 Jan 2021 18:19:31 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)     | 17 Sep 2020 13:28:20 |
| User entered 'Yes (Y)'    | Emily Carney (b) (4)<br>(b) (4) | 31 Aug 2020 17:02:20 |

**US3802074**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:55:48**

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 11:19:23 |
| User entered 'I'  | System           | 31 Aug 2020 17:02:20 |

US3802074

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:55:48

**TIMEPOINT**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| Data entry locked.   | System           | 31 Aug 2020 13:54:40 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System           | 31 Aug 2020 13:54:40 |

US3802074

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:55:48

Was **TEMPERATURE** taken?

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-08-31T10:20:40', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '0a281e65-72c9-45f8-a12a-fa11939b25f8' User entered 'Yes (Y)' | System           | 31 Aug 2020 14:21:14 |
|   | System           | 31 Aug 2020 14:21:14 |

US3802074

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:55:48

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-08-31T10:20:56', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '0a281e65-72c9-45f8-a12a-fa11939b25f8' User entered '96.7' | System           | 31 Aug 2020 14:21:14 |
|  | System           | 31 Aug 2020 14:21:14 |



US3802074

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:55:48

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-08-31T10:21:03', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '0a281e65-72c9-45f8-a12a-fa11939b25f8' | System           | 31 Aug 2020 14:21:14 |
| User entered 'No (N)'  | System           | 31 Aug 2020 14:21:14 |

US3802074

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:55:48

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-08-31T10:21:11', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '0a281e65-72c9-45f8-a12a-fa11939b25f8' User entered '31 Aug 2020 10:21' | System           | 31 Aug 2020 14:21:14 |
|   | System           | 31 Aug 2020 14:21:14 |

**US3802074**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 09:55:48**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| User entered '31 Aug 2020 10:05' | System           | 31 Aug 2020 13:54:40 |

US3802074

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:55:48

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| User entered '31 Aug 2020 12:35' | System           | 31 Aug 2020 13:54:40 |

US3802074

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:55:48

**TIMEPOINT**

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                                 | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| Data entry locked.                                | System           | 31 Aug 2020 13:54:40 |
| User entered 'Day 1, after vaccination (at home)' | System           | 31 Aug 2020 13:54:40 |

US3802074

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:55:48

Was **TEMPERATURE** taken?

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-08-31T19:19:16', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '6ddb476c-38fe-46de-a3a3-d9693b00b67d' User entered 'Yes (Y)' | System           | 31 Aug 2020 23:19:37 |
|   | System           | 31 Aug 2020 23:19:37 |

US3802074

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:55:48

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-08-31T19:19:24', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '6ddb476c-38fe-46de-a3a3-d9693b00b67d' User entered '97.9' | System           | 31 Aug 2020 23:19:37 |
|  | System           | 31 Aug 2020 23:19:37 |

US3802074

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:55:48

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-08-31T19:19:29', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '6ddb476c-38fe-46de-a3a3-d9693b00b67d' User entered 'No (N)' | System           | 31 Aug 2020 23:19:37 |
|  | System           | 31 Aug 2020 23:19:37 |



**US3802074**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 09:55:48**

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-08-31T19:19:34', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '6ddb476c-38fe-46de-a3a3-d9693b00b67d' User entered '31 Aug 2020 19:19' | System           | 31 Aug 2020 23:19:37 |
|   | System           | 31 Aug 2020 23:19:37 |

**US3802074**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 09:55:48**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| User entered '31 Aug 2020 13:30' | System           | 31 Aug 2020 13:54:40 |

US3802074

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:55:48

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| User entered '01 Sep 2020 11:59' | System           | 31 Aug 2020 13:54:40 |

US3802074

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:55:48

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| Data entry locked.   | System           | 31 Aug 2020 13:54:40 |
| User entered 'Day 2' | System           | 31 Aug 2020 13:54:40 |

US3802074

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:55:48

Was **TEMPERATURE** taken?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-09-01T19:00:03', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '66910602-69b7-48e3-a1ba-078084f06b77' | System           | 01 Sep 2020 23:00:52 |
| User entered 'Yes (Y)'   | System           | 01 Sep 2020 23:00:52 |

US3802074

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:55:48

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-09-01T19:00:30', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '66910602-69b7-48e3-a1ba-078084f06b77' User entered '98.1' | System           | 01 Sep 2020 23:00:52 |
|  | System           | 01 Sep 2020 23:00:52 |

US3802074

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:55:48

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-09-01T19:00:34', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '66910602-69b7-48e3-a1ba-078084f06b77' | System           | 01 Sep 2020 23:00:52 |
| User entered 'Yes (Y)'   | System           | 01 Sep 2020 23:00:52 |

US3802074

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:55:48

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

| Audit   | User                  | Time (GMT)           |
|---|-----------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)      | 06 Mar 2021 23:14:58 |
| User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'contacted' (Site from System). | (b) (4)               | 08 Oct 2020 15:00:46 |
| User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).  | Jennifer Nagg (b) (4) | 05 Oct 2020 20:40:30 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-09-01T19:00:42', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '66910602-69b7-48e3-a1ba-078084f06b77'  | System                | 01 Sep 2020 23:00:52 |
| User entered '1'  | System                | 01 Sep 2020 23:00:52 |



US3802074

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:55:48

To **PREVENT** pain or fever from occurring

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-09-01T19:00:42', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '66910602-69b7-48e3-a1ba-078084f06b77' User entered '0' | System           | 01 Sep 2020 23:00:52 |
|   | System           | 01 Sep 2020 23:00:52 |

**US3802074**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 10 Jun 2021 09:55:48**

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-09-01T19:00:51', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '66910602-69b7-48e3-a1ba-078084f06b77' | System           | 01 Sep 2020 23:00:52 |
| User entered '01 Sep 2020 19:00'   | System           | 01 Sep 2020 23:00:52 |

US3802074

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:55:48

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| User entered '01 Sep 2020 12:00' | System           | 31 Aug 2020 13:54:40 |

**US3802074**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 10 Jun 2021 09:55:48**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| User entered '02 Sep 2020 11:59' | System           | 31 Aug 2020 13:54:40 |

US3802074

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:55:48

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| Data entry locked.   | System           | 31 Aug 2020 13:54:40 |
| User entered 'Day 3' | System           | 31 Aug 2020 13:54:40 |

US3802074

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:55:48

Was **TEMPERATURE** taken?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-09-02T22:09:26', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '2e0ae0af-8fcc-4c47-94bd-b54fb671acf5' | System           | 03 Sep 2020 02:09:45 |
| User entered 'Yes (Y)'   | System           | 03 Sep 2020 02:09:45 |

US3802074

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:55:48

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-09-02T22:09:37', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '2e0ae0af-8fcc-4c47-94bd-b54fb671acf5' User entered '97.1' | System           | 03 Sep 2020 02:09:45 |
|  | System           | 03 Sep 2020 02:09:45 |

US3802074

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:55:48

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-09-02T22:09:41', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '2e0ae0af-8fcc-4c47-94bd-b54fb671acf5' | System           | 03 Sep 2020 02:09:45 |
| User entered 'No (N)'  | System           | 03 Sep 2020 02:09:45 |



**US3802074**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 09:55:48**

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-09-02T22:09:44', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '2e0ae0af-8fcc-4c47-94bd-b54fb671acf5' | System           | 03 Sep 2020 02:09:45 |
| User entered '02 Sep 2020 22:09'   | System           | 03 Sep 2020 02:09:45 |

US3802074

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:55:48

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| User entered '02 Sep 2020 12:00' | System           | 31 Aug 2020 13:54:40 |

US3802074

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:55:48

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| User entered '03 Sep 2020 11:59' | System           | 31 Aug 2020 13:54:40 |

US3802074

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:55:48

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| Data entry locked.   | System           | 31 Aug 2020 13:54:40 |
| User entered 'Day 4' | System           | 31 Aug 2020 13:54:40 |

US3802074

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:55:48

Was **TEMPERATURE** taken?

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-09-03T18:42:21', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '145162ec-6db1-46b8-8f84-9f032e5813f1' User entered 'Yes (Y)' | System           | 03 Sep 2020 22:42:37 |
|   | System           | 03 Sep 2020 22:42:37 |

US3802074

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:55:48

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-09-03T18:42:27', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '145162ec-6db1-46b8-8f84-9f032e5813f1' User entered '97.1' | System           | 03 Sep 2020 22:42:37 |

US3802074

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:55:48

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-09-03T18:42:31', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '145162ec-6db1-46b8-8f84-9f032e5813f1' User entered 'No (N)' | System           | 03 Sep 2020 22:42:37 |

**US3802074**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 10 Jun 2021 09:55:48**

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-09-03T18:42:35', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '145162ec-6db1-46b8-8f84-9f032e5813f1' User entered '03 Sep 2020 18:42' | System           | 03 Sep 2020 22:42:37 |
|   | System           | 03 Sep 2020 22:42:37 |



**US3802074**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 10 Jun 2021 09:55:48**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| User entered '03 Sep 2020 12:00' | System           | 31 Aug 2020 13:54:40 |

US3802074

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:55:48

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| User entered '04 Sep 2020 11:59' | System           | 31 Aug 2020 13:54:40 |

US3802074

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:55:48

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| Data entry locked.   | System           | 31 Aug 2020 13:54:40 |
| User entered 'Day 5' | System           | 31 Aug 2020 13:54:40 |

US3802074

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:55:48

Was **TEMPERATURE** taken?

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-09-04T19:36:47', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '17d40574-f936-4705-aa10-2db55230cf0d' User entered 'Yes (Y)' | System           | 04 Sep 2020 23:37:03 |
|   | System           | 04 Sep 2020 23:37:03 |

US3802074

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:55:48

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-09-04T19:36:52', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '17d40574-f936-4705-aa10-2db55230cf0d' User entered '97.1' | System           | 04 Sep 2020 23:37:03 |
|  | System           | 04 Sep 2020 23:37:03 |

US3802074

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:55:48

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-09-04T19:36:55', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '17d40574-f936-4705-aa10-2db55230cf0d' | System           | 04 Sep 2020 23:37:03 |
| User entered 'No (N)'  | System           | 04 Sep 2020 23:37:03 |

**US3802074**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 09:55:48**

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-09-04T19:36:59', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '17d40574-f936-4705-aa10-2db55230cf0d' User entered '04 Sep 2020 19:36' | System           | 04 Sep 2020 23:37:03 |
|   | System           | 04 Sep 2020 23:37:03 |

US3802074

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:55:48

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| User entered '04 Sep 2020 12:00' | System           | 31 Aug 2020 13:54:40 |



**US3802074**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 09:55:48**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| User entered '05 Sep 2020 11:59' | System           | 31 Aug 2020 13:54:40 |

US3802074

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:55:48

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| Data entry locked.   | System           | 31 Aug 2020 13:54:40 |
| User entered 'Day 6' | System           | 31 Aug 2020 13:54:40 |

US3802074

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:55:48

Was **TEMPERATURE** taken?

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-09-05T18:44:58', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '9663daff-06eb-4c9e-a12b-5d4a06c09bf0' User entered 'Yes (Y)' | System           | 05 Sep 2020 22:45:14 |
|   | System           | 05 Sep 2020 22:45:14 |

US3802074

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:55:48

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-09-05T18:45:05', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '9663daff-06eb-4c9e-a12b-5d4a06c09bf0' User entered '97.6' | System           | 05 Sep 2020 22:45:14 |
|  | System           | 05 Sep 2020 22:45:14 |

US3802074

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:55:48

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-09-05T18:45:08', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '9663daff-06eb-4c9e-a12b-5d4a06c09bf0' | System           | 05 Sep 2020 22:45:14 |
| User entered 'No (N)'  | System           | 05 Sep 2020 22:45:14 |

**US3802074**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 09:55:48**

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-09-05T18:45:11', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '9663daff-06eb-4c9e-a12b-5d4a06c09bf0' User entered '05 Sep 2020 18:45' | System           | 05 Sep 2020 22:45:14 |
|   | System           | 05 Sep 2020 22:45:14 |

US3802074

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:55:48

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| User entered '05 Sep 2020 12:00' | System           | 31 Aug 2020 13:54:40 |

**US3802074**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 09:55:48**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| User entered '06 Sep 2020 11:59' | System           | 31 Aug 2020 13:54:40 |



US3802074

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:55:48

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| Data entry locked.   | System           | 31 Aug 2020 13:54:40 |
| User entered 'Day 7' | System           | 31 Aug 2020 13:54:40 |

US3802074

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:55:48

Was **TEMPERATURE** taken?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-09-06T18:41:33', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '87e9ebb9-fdf2-4c43-9ff1-7a28745917b7' | System           | 06 Sep 2020 22:42:22 |
| User entered 'Yes (Y)'   | System           | 06 Sep 2020 22:42:22 |

US3802074

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:55:48

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-09-06T18:41:39', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '87e9ebb9-fdf2-4c43-9ff1-7a28745917b7' User entered '97.7' | System           | 06 Sep 2020 22:42:22 |
|  | System           | 06 Sep 2020 22:42:22 |

US3802074

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:55:48

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-09-06T18:41:54', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '87e9ebb9-fdf2-4c43-9ff1-7a28745917b7' | System           | 06 Sep 2020 22:42:22 |
| User entered 'Yes (Y)'   | System           | 06 Sep 2020 22:42:22 |

US3802074

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:55:48

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

| Audit   | User                  | Time (GMT)           |
|---|-----------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)      | 06 Mar 2021 23:14:58 |
| User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'entered' (Site from System). | (b) (4)               | 08 Oct 2020 15:00:56 |
| User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).  | Jennifer Nagg (b) (4) | 05 Oct 2020 20:41:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-09-06T18:42:06', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '87e9ebb9-fdf2-4c43-9ff1-7a28745917b7'  | System                | 06 Sep 2020 22:42:22 |
| User entered '1'  | System                | 06 Sep 2020 22:42:22 |

US3802074

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:55:48

To **PREVENT** pain or fever from occurring

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-09-06T18:42:06', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '87e9ebb9-fdf2-4c43-9ff1-7a28745917b7' User entered '0' | System           | 06 Sep 2020 22:42:22 |
|   | System           | 06 Sep 2020 22:42:22 |

**US3802074**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 09:55:48**

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-09-06T18:42:19', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '87e9ebb9-fdf2-4c43-9ff1-7a28745917b7' User entered '06 Sep 2020 18:42' | System           | 06 Sep 2020 22:42:22 |
|   | System           | 06 Sep 2020 22:42:22 |

US3802074

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:55:48

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| User entered '06 Sep 2020 12:00' | System           | 31 Aug 2020 13:54:40 |



**US3802074**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 09:55:48**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| User entered '07 Sep 2020 11:59' | System           | 31 Aug 2020 13:54:40 |

US3802074

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(8)

Generated On: 10 Jun 2021 09:55:48

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| Data entry locked.   | System           | 06 Sep 2020 22:42:22 |
| User entered 'Day 8' | System           | 06 Sep 2020 22:42:22 |

US3802074

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(8)

Generated On: 10 Jun 2021 09:55:48

Was **TEMPERATURE** taken?

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-09-07T17:29:40', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '0bf36c74-2627-4a5e-a741-9d4b5f84ee3f' User entered 'Yes (Y)' | System           | 07 Sep 2020 21:29:54 |
|   | System           | 07 Sep 2020 21:29:54 |

US3802074

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(8)

Generated On: 10 Jun 2021 09:55:48

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-09-07T17:29:46', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '0bf36c74-2627-4a5e-a741-9d4b5f84ee3f' User entered '97.2' | System           | 07 Sep 2020 21:29:54 |
|  | System           | 07 Sep 2020 21:29:54 |

US3802074

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(8)

Generated On: 10 Jun 2021 09:55:48

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-09-07T17:29:49', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '0bf36c74-2627-4a5e-a741-9d4b5f84ee3f' User entered 'No (N)' | System           | 07 Sep 2020 21:29:54 |
|  | System           | 07 Sep 2020 21:29:54 |

**US3802074**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(8)**

**Generated On: 10 Jun 2021 09:55:48**

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-09-07T17:29:53', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '0bf36c74-2627-4a5e-a741-9d4b5f84ee3f' User entered '07 Sep 2020 17:29' | System           | 07 Sep 2020 21:29:54 |
|   | System           | 07 Sep 2020 21:29:54 |

US3802074

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(8)

Generated On: 10 Jun 2021 09:55:48

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| User entered '07 Sep 2020 12:00' | System           | 06 Sep 2020 22:42:22 |

US3802074

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(8)

Generated On: 10 Jun 2021 09:55:48

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| User entered '08 Sep 2020 11:59' | System           | 06 Sep 2020 22:42:22 |



US3802074

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:55:48

**TIMEPOINT**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:48 |
| Data entry locked.   | System           | 31 Aug 2020 13:54:40 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System           | 31 Aug 2020 13:54:40 |

US3802074

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:55:48

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:48 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-08-31T10:21:22', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '2b51be4f-a6eb-42e5-b713-d6a883ebd091' | System           | 31 Aug 2020 14:21:38 |
| User entered 'None (1)'  | System           | 31 Aug 2020 14:21:38 |

US3802074

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:55:48

Is there any REDNESS AT INJECTION SITE?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:48 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-08-31T10:21:25', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '2b51be4f-a6eb-42e5-b713-d6a883ebd091' | System           | 31 Aug 2020 14:21:38 |
| User entered 'No (N)'  | System           | 31 Aug 2020 14:21:38 |

US3802074

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:55:48

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:48 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-08-31T10:21:28', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '2b51be4f-a6eb-42e5-b713-d6a883ebd091' | System           | 31 Aug 2020 14:21:38 |
| User entered 'No (N)'  | System           | 31 Aug 2020 14:21:38 |

US3802074

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:55:48

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:48 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-08-31T10:21:31', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '2b51be4f-a6eb-42e5-b713-d6a883ebd091' | System           | 31 Aug 2020 14:21:38 |
| User entered 'None (1)'  | System           | 31 Aug 2020 14:21:38 |

**US3802074**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 09:55:48**

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:48 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-08-31T10:21:36', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '2b51be4f-a6eb-42e5-b713-d6a883ebd091' | System           | 31 Aug 2020 14:21:38 |
| User entered '31 Aug 2020 10:21'   | System           | 31 Aug 2020 14:21:38 |

**US3802074**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 09:55:48**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:14:48 |
| User entered '31 Aug 2020 10:05' | System           | 31 Aug 2020 13:54:40 |

US3802074

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:55:48

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:14:48 |
| User entered '31 Aug 2020 12:35' | System           | 31 Aug 2020 13:54:40 |



US3802074

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:55:48

**TIMEPOINT**

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                                 | (b) (4), (b) (6) | 06 Mar 2021 23:14:48 |
| Data entry locked.                                | System           | 31 Aug 2020 13:54:40 |
| User entered 'Day 1, after vaccination (at home)' | System           | 31 Aug 2020 13:54:40 |

US3802074

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:55:48

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:48 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-08-31T19:19:52', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '1a627c5a-c649-4d1d-b5ba-9c5e19192ef2' | System           | 31 Aug 2020 23:20:12 |
| User entered 'Does not interfere with activity (2)'  | System           | 31 Aug 2020 23:20:12 |

US3802074

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:55:48

Is there any REDNESS AT INJECTION SITE?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:48 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-08-31T19:19:56', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '1a627c5a-c649-4d1d-b5ba-9c5e19192ef2' User entered 'No (N)' | System           | 31 Aug 2020 23:20:12 |
|  | System           | 31 Aug 2020 23:20:12 |

US3802074

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:55:48

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:48 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-08-31T19:20:01', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '1a627c5a-c649-4d1d-b5ba-9c5e19192ef2' | System           | 31 Aug 2020 23:20:12 |
| User entered 'No (N)'  | System           | 31 Aug 2020 23:20:12 |

US3802074

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:55:48

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:48 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-08-31T19:20:05', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '1a627c5a-c649-4d1d-b5ba-9c5e19192ef2' | System           | 31 Aug 2020 23:20:12 |
| User entered 'None (1)'  | System           | 31 Aug 2020 23:20:12 |

**US3802074**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 09:55:48**

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:48 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-08-31T19:20:08', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '1a627c5a-c649-4d1d-b5ba-9c5e19192ef2' | System           | 31 Aug 2020 23:20:12 |
| User entered '31 Aug 2020 19:20'   | System           | 31 Aug 2020 23:20:12 |

**US3802074**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 09:55:48**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:14:48 |
| User entered '31 Aug 2020 13:30' | System           | 31 Aug 2020 13:54:40 |

US3802074

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:55:48

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:14:48 |
| User entered '01 Sep 2020 11:59' | System           | 31 Aug 2020 13:54:40 |



US3802074

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:55:48

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 06 Mar 2021 23:14:48 |
| Data entry locked.   | System           | 31 Aug 2020 13:54:40 |
| User entered 'Day 2' | System           | 31 Aug 2020 13:54:40 |

US3802074

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:55:48

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:48 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-09-01T19:01:28', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '57730b45-0fba-4c90-8ef9-ac32e3fc8356' | System           | 01 Sep 2020 23:02:36 |
| User entered 'Does not interfere with activity (2)'  | System           | 01 Sep 2020 23:02:36 |

US3802074

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:55:48

Is there any REDNESS AT INJECTION SITE?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:48 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-09-01T19:01:33', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '57730b45-0fba-4c90-8ef9-ac32e3fc8356' | System           | 01 Sep 2020 23:02:36 |
| User entered 'No (N)'  | System           | 01 Sep 2020 23:02:36 |

US3802074

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:55:48

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:48 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-09-01T19:02:17', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '57730b45-0fba-4c90-8ef9-ac32e3fc8356' | System           | 01 Sep 2020 23:02:36 |
| User entered 'No (N)'  | System           | 01 Sep 2020 23:02:36 |

US3802074

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:55:48

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:48 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-09-01T19:02:24', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '57730b45-0fba-4c90-8ef9-ac32e3fc8356' | System           | 01 Sep 2020 23:02:36 |
| User entered 'None (1)'  | System           | 01 Sep 2020 23:02:36 |

**US3802074**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 09:55:48**

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 06 Mar 2021 23:14:48 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-09-01T19:02:31', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '57730b45-0fba-4c90-8ef9-ac32e3fc8356' User entered '01 Sep 2020 19:02' | System           | 01 Sep 2020 23:02:36 |
|   | System           | 01 Sep 2020 23:02:36 |

**US3802074**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 09:55:48**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:14:48 |
| User entered '01 Sep 2020 12:00' | System           | 31 Aug 2020 13:54:40 |

**US3802074**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 09:55:48**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:14:48 |
| User entered '02 Sep 2020 11:59' | System           | 31 Aug 2020 13:54:40 |



**US3802074**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 09:55:48**

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 06 Mar 2021 23:14:48 |
| Data entry locked.   | System           | 31 Aug 2020 13:54:40 |
| User entered 'Day 3' | System           | 31 Aug 2020 13:54:40 |

US3802074

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:55:48

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:48 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-09-02T22:09:58', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: 'eaac974f-2404-49c5-929d-0c40fef4b1eb' User entered 'None (1)' | System           | 03 Sep 2020 02:10:12 |
|  | System           | 03 Sep 2020 02:10:12 |

US3802074

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:55:48

Is there any REDNESS AT INJECTION SITE?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:48 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-09-02T22:10:00', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: 'eaac974f-2404-49c5-929d-0c40fef4b1eb' User entered 'No (N)' | System           | 03 Sep 2020 02:10:12 |
|  | System           | 03 Sep 2020 02:10:12 |

US3802074

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:55:48

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:48 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-09-02T22:10:03', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: 'eaac974f-2404-49c5-929d-0c40fef4b1eb' User entered 'No (N)' | System           | 03 Sep 2020 02:10:12 |
|  | System           | 03 Sep 2020 02:10:12 |

US3802074

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:55:48

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:48 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-09-02T22:10:06', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: 'eaac974f-2404-49c5-929d-0c40fef4b1eb' User entered 'None (1)' | System           | 03 Sep 2020 02:10:12 |
|  | System           | 03 Sep 2020 02:10:12 |

**US3802074**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 09:55:48**

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 06 Mar 2021 23:14:48 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-09-02T22:10:09', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: 'eaac974f-2404-49c5-929d-0c40fef4b1eb' User entered '02 Sep 2020 22:10' | System           | 03 Sep 2020 02:10:12 |
|   | System           | 03 Sep 2020 02:10:12 |

US3802074

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:55:48

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:14:48 |
| User entered '02 Sep 2020 12:00' | System           | 31 Aug 2020 13:54:40 |

**US3802074**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 09:55:48**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:14:48 |
| User entered '03 Sep 2020 11:59' | System           | 31 Aug 2020 13:54:40 |



US3802074

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:55:48

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 06 Mar 2021 23:14:48 |
| Data entry locked.   | System           | 31 Aug 2020 13:54:40 |
| User entered 'Day 4' | System           | 31 Aug 2020 13:54:40 |

US3802074

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:55:48

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:48 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-09-03T18:42:38', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '7054a762-2c96-49e9-a87f-d8303d319157' | System           | 03 Sep 2020 22:43:04 |
| User entered 'None (1)'  | System           | 03 Sep 2020 22:43:04 |

US3802074

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:55:48

Is there any REDNESS AT INJECTION SITE?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:48 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-09-03T18:42:51', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '7054a762-2c96-49e9-a87f-d8303d319157' | System           | 03 Sep 2020 22:43:04 |
| User entered 'No (N)'  | System           | 03 Sep 2020 22:43:04 |

US3802074

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:55:48

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:48 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-09-03T18:42:53', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '7054a762-2c96-49e9-a87f-d8303d319157' | System           | 03 Sep 2020 22:43:04 |
| User entered 'No (N)'  | System           | 03 Sep 2020 22:43:04 |

US3802074

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:55:48

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:48 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-09-03T18:42:56', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '7054a762-2c96-49e9-a87f-d8303d319157' | System           | 03 Sep 2020 22:43:04 |
| User entered 'None (1)'  | System           | 03 Sep 2020 22:43:04 |

**US3802074**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 09:55:48**

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 06 Mar 2021 23:14:48 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-09-03T18:43:03', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '7054a762-2c96-49e9-a87f-d8303d319157' User entered '03 Sep 2020 18:43' | System           | 03 Sep 2020 22:43:04 |
|   | System           | 03 Sep 2020 22:43:04 |

**US3802074**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 09:55:48**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:14:48 |
| User entered '03 Sep 2020 12:00' | System           | 31 Aug 2020 13:54:40 |

**US3802074**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 09:55:48**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:14:48 |
| User entered '04 Sep 2020 11:59' | System           | 31 Aug 2020 13:54:40 |



US3802074

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:55:48

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 06 Mar 2021 23:14:48 |
| Data entry locked.   | System           | 31 Aug 2020 13:54:40 |
| User entered 'Day 5' | System           | 31 Aug 2020 13:54:40 |

US3802074

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:55:48

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:48 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-09-04T19:37:03', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '90beabf1-6c8f-4fe5-a5c2-dee309f4f2e9' | System           | 04 Sep 2020 23:37:17 |
| User entered 'None (1)'  | System           | 04 Sep 2020 23:37:17 |

US3802074

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:55:48

Is there any REDNESS AT INJECTION SITE?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:48 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-09-04T19:37:06', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '90beabf1-6c8f-4fe5-a5c2-dee309f4f2e9' | System           | 04 Sep 2020 23:37:17 |
| User entered 'No (N)'  | System           | 04 Sep 2020 23:37:17 |

US3802074

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:55:48

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:48 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-09-04T19:37:08', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '90beabf1-6c8f-4fe5-a5c2-dee309f4f2e9' | System           | 04 Sep 2020 23:37:17 |
| User entered 'No (N)'  | System           | 04 Sep 2020 23:37:17 |

US3802074

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:55:48

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:48 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-09-04T19:37:11', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '90beabf1-6c8f-4fe5-a5c2-dee309f4f2e9' | System           | 04 Sep 2020 23:37:17 |
| User entered 'None (1)'  | System           | 04 Sep 2020 23:37:17 |

**US3802074**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:55:48**

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:48 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-09-04T19:37:14', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '90beabf1-6c8f-4fe5-a5c2-dee309f4f2e9' | System           | 04 Sep 2020 23:37:17 |
| User entered '04 Sep 2020 19:37'   | System           | 04 Sep 2020 23:37:17 |

US3802074

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:55:48

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:14:48 |
| User entered '04 Sep 2020 12:00' | System           | 31 Aug 2020 13:54:40 |

**US3802074**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:55:48**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:14:48 |
| User entered '05 Sep 2020 11:59' | System           | 31 Aug 2020 13:54:40 |



US3802074

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:55:48

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 06 Mar 2021 23:14:48 |
| Data entry locked.   | System           | 31 Aug 2020 13:54:40 |
| User entered 'Day 6' | System           | 31 Aug 2020 13:54:40 |

US3802074

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:55:48

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:48 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-09-05T18:45:15', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: 'e9f189ef-e45d-49aa-bd8b-aadc8353b9e2' | System           | 05 Sep 2020 22:45:29 |
| User entered 'None (1)'  | System           | 05 Sep 2020 22:45:29 |

US3802074

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:55:48

Is there any REDNESS AT INJECTION SITE?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:48 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-09-05T18:45:19', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: 'e9f189ef-e45d-49aa-bd8b-aadc8353b9e2' | System           | 05 Sep 2020 22:45:29 |
| User entered 'No (N)'  | System           | 05 Sep 2020 22:45:29 |

US3802074

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:55:48

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:48 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-09-05T18:45:21', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: 'e9f189ef-e45d-49aa-bd8b-aadc8353b9e2' | System           | 05 Sep 2020 22:45:29 |
| User entered 'No (N)'  | System           | 05 Sep 2020 22:45:29 |

US3802074

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:55:48

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:48 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-09-05T18:45:23', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: 'e9f189ef-e45d-49aa-bd8b-aadc8353b9e2' | System           | 05 Sep 2020 22:45:29 |
| User entered 'None (1)'  | System           | 05 Sep 2020 22:45:29 |

**US3802074**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:55:48**

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:48 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-09-05T18:45:26', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: 'e9f189ef-e45d-49aa-bd8b-aadc8353b9e2' | System           | 05 Sep 2020 22:45:29 |
| User entered '05 Sep 2020 18:45'   | System           | 05 Sep 2020 22:45:29 |

**US3802074**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:55:48**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:14:48 |
| User entered '05 Sep 2020 12:00' | System           | 31 Aug 2020 13:54:40 |

US3802074

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:55:48

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:14:48 |
| User entered '06 Sep 2020 11:59' | System           | 31 Aug 2020 13:54:40 |



**US3802074**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 09:55:48**

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 06 Mar 2021 23:14:48 |
| Data entry locked.   | System           | 31 Aug 2020 13:54:40 |
| User entered 'Day 7' | System           | 31 Aug 2020 13:54:40 |

US3802074

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:55:48

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

Please select one response below

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 06 Mar 2021 23:14:48 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-09-06T18:42:23', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '84dcae0-2d47-46cb-9c46-caad2c20a9c6' User entered 'None (1)' | System           | 06 Sep 2020 22:42:37 |
|   | System           | 06 Sep 2020 22:42:37 |

US3802074

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:55:48

Is there any REDNESS AT INJECTION SITE?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:48 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-09-06T18:42:27', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '84dcaae0-2d47-46cb-9c46-caad2c20a9c6' User entered 'No (N)' | System           | 06 Sep 2020 22:42:37 |
|  | System           | 06 Sep 2020 22:42:37 |

US3802074

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:55:48

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:48 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-09-06T18:42:29', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '84dcaae0-2d47-46cb-9c46-caad2c20a9c6' User entered 'No (N)' | System           | 06 Sep 2020 22:42:37 |
|  | System           | 06 Sep 2020 22:42:37 |

US3802074

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:55:48

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

Please select one response below

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 06 Mar 2021 23:14:48 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-09-06T18:42:32', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '84dcae0-2d47-46cb-9c46-caad2c20a9c6' | System           | 06 Sep 2020 22:42:37 |
| User entered 'None (1)'   | System           | 06 Sep 2020 22:42:37 |

**US3802074**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 09:55:48**

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 06 Mar 2021 23:14:48 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-09-06T18:42:34', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '84dcaae0-2d47-46cb-9c46-caad2c20a9c6' User entered '06 Sep 2020 18:42' | System           | 06 Sep 2020 22:42:37 |
|   | System           | 06 Sep 2020 22:42:37 |

**US3802074**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 09:55:48**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:14:48 |
| User entered '06 Sep 2020 12:00' | System           | 31 Aug 2020 13:54:40 |

**US3802074**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 09:55:48**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:14:48 |
| User entered '07 Sep 2020 11:59' | System           | 31 Aug 2020 13:54:40 |



US3802074

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:55:48

**TIMEPOINT**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:48 |
| Data entry locked.   | System           | 31 Aug 2020 13:54:40 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System           | 31 Aug 2020 13:54:40 |

US3802074

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:55:48

**HEADACHE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:48 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-08-31T10:21:43', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '73d701c6-93b4-4c57-8c20-b786e4d663d3' User entered 'None (0)' | System           | 31 Aug 2020 14:22:06 |
|  | System           | 31 Aug 2020 14:22:06 |

**US3802074**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:55:48**

**FATIGUE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:48 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-08-31T10:21:46', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '73d701c6-93b4-4c57-8c20-b786e4d663d3' User entered 'None (0)' | System           | 31 Aug 2020 14:22:06 |
|  | System           | 31 Aug 2020 14:22:06 |

US3802074

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:55:48

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:48 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-08-31T10:21:48', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '73d701c6-93b4-4c57-8c20-b786e4d663d3' User entered 'None (0)' | System           | 31 Aug 2020 14:22:06 |
|  | System           | 31 Aug 2020 14:22:06 |

US3802074

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:55:48

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:48 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-08-31T10:21:49', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '73d701c6-93b4-4c57-8c20-b786e4d663d3' User entered 'None (0)' | System           | 31 Aug 2020 14:22:06 |
|  | System           | 31 Aug 2020 14:22:06 |

US3802074

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:55:48

**NAUSEA/VOMITING**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:48 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-08-31T10:21:52', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '73d701c6-93b4-4c57-8c20-b786e4d663d3' User entered 'None (0)' | System           | 31 Aug 2020 14:22:06 |
|  | System           | 31 Aug 2020 14:22:06 |

**US3802074**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:55:48**

**CHILLS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:48 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-08-31T10:21:54', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '73d701c6-93b4-4c57-8c20-b786e4d663d3' User entered 'None (0)' | System           | 31 Aug 2020 14:22:06 |
|  | System           | 31 Aug 2020 14:22:06 |

US3802074

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:55:48

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:48 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-08-31T10:21:58', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '73d701c6-93b4-4c57-8c20-b786e4d663d3' | System           | 31 Aug 2020 14:22:06 |
| User entered 'No (N)'  | System           | 31 Aug 2020 14:22:06 |



US3802074

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:55:48

[PC Time stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 06 Mar 2021 23:14:48 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-08-31T10:22:04', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '73d701c6-93b4-4c57-8c20-b786e4d663d3' User entered '31 Aug 2020 10:22' | System           | 31 Aug 2020 14:22:06 |
|   | System           | 31 Aug 2020 14:22:06 |

**US3802074**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:55:48**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:14:48 |
| User entered '31 Aug 2020 10:05' | System           | 31 Aug 2020 13:54:40 |

**US3802074**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:55:48**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:14:48 |
| User entered '31 Aug 2020 12:35' | System           | 31 Aug 2020 13:54:40 |

US3802074

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:55:48

**TIMEPOINT**

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                                 | (b) (4), (b) (6) | 06 Mar 2021 23:14:48 |
| Data entry locked.                                | System           | 31 Aug 2020 13:54:40 |
| User entered 'Day 1, after vaccination (at home)' | System           | 31 Aug 2020 13:54:40 |

**US3802074**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:55:48**

**HEADACHE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:48 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-08-31T19:20:13', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '16cf628d-1da1-470e-b8c9-0dd518adcf0e' User entered 'None (0)' | System           | 31 Aug 2020 23:20:40 |
|  | System           | 31 Aug 2020 23:20:40 |

US3802074

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:55:48

**FATIGUE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:48 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-08-31T19:20:15', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '16cf628d-1da1-470e-b8c9-0dd518adcf0e' User entered 'None (0)' | System           | 31 Aug 2020 23:20:40 |
|  | System           | 31 Aug 2020 23:20:40 |

US3802074

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:55:48

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:48 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-08-31T19:20:18', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '16cf628d-1da1-470e-b8c9-0dd518adcf0e' User entered 'None (0)' | System           | 31 Aug 2020 23:20:40 |
|  | System           | 31 Aug 2020 23:20:40 |

US3802074

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:55:48

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:48 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-08-31T19:20:21', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '16cf628d-1da1-470e-b8c9-0dd518adcf0e' User entered 'None (0)' | System           | 31 Aug 2020 23:20:40 |
|  | System           | 31 Aug 2020 23:20:40 |



US3802074

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:55:48

**NAUSEA/VOMITING**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:48 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-08-31T19:20:23', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '16cf628d-1da1-470e-b8c9-0dd518adcf0e' User entered 'None (0)' | System           | 31 Aug 2020 23:20:40 |
|  | System           | 31 Aug 2020 23:20:40 |

**US3802074**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:55:48**

**CHILLS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:48 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-08-31T19:20:25', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '16cf628d-1da1-470e-b8c9-0dd518adcf0e' User entered 'None (0)' | System           | 31 Aug 2020 23:20:40 |
|  | System           | 31 Aug 2020 23:20:40 |

US3802074

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:55:48

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:48 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-08-31T19:20:34', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '16cf628d-1da1-470e-b8c9-0dd518adcf0e' User entered 'No (N)' | System           | 31 Aug 2020 23:20:40 |
|  | System           | 31 Aug 2020 23:20:40 |

**US3802074**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:55:48**

[PC Time stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 06 Mar 2021 23:14:48 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-08-31T19:20:37', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '16cf628d-1da1-470e-b8c9-0dd518adcf0e' User entered '31 Aug 2020 19:20' | System           | 31 Aug 2020 23:20:40 |
|   | System           | 31 Aug 2020 23:20:40 |

**US3802074**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:55:48**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:14:48 |
| User entered '31 Aug 2020 13:30' | System           | 31 Aug 2020 13:54:40 |

**US3802074**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:55:48**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:14:48 |
| User entered '01 Sep 2020 11:59' | System           | 31 Aug 2020 13:54:40 |

US3802074

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:55:48

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 06 Mar 2021 23:14:48 |
| Data entry locked.   | System           | 31 Aug 2020 13:54:40 |
| User entered 'Day 2' | System           | 31 Aug 2020 13:54:40 |

**US3802074**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:55:48**

**HEADACHE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:48 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-09-01T19:02:39', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '0a7e1bd1-04a0-48d9-9504-464e68dda8f4' User entered 'None (0)' | System           | 01 Sep 2020 23:03:16 |
|  | System           | 01 Sep 2020 23:03:16 |



**US3802074**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:55:48**

**FATIGUE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:48 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-09-01T19:02:48', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '0a7e1bd1-04a0-48d9-9504-464e68dda8f4' | System           | 01 Sep 2020 23:03:16 |
| User entered 'No interference with activity (1)'   | System           | 01 Sep 2020 23:03:16 |

US3802074

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:55:48

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:48 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-09-01T19:02:53', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '0a7e1bd1-04a0-48d9-9504-464e68dda8f4' User entered 'None (0)' | System           | 01 Sep 2020 23:03:16 |
|  | System           | 01 Sep 2020 23:03:16 |

US3802074

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:55:48

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:48 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-09-01T19:02:56', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '0a7e1bd1-04a0-48d9-9504-464e68dda8f4' User entered 'None (0)' | System           | 01 Sep 2020 23:03:16 |
|  | System           | 01 Sep 2020 23:03:16 |

**US3802074**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:55:48**

**NAUSEA/VOMITING**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:48 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-09-01T19:02:58', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '0a7e1bd1-04a0-48d9-9504-464e68dda8f4' User entered 'None (0)' | System           | 01 Sep 2020 23:03:16 |
|  | System           | 01 Sep 2020 23:03:16 |

**US3802074**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:55:48**

**CHILLS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:48 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-09-01T19:03:01', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '0a7e1bd1-04a0-48d9-9504-464e68dda8f4' User entered 'None (0)' | System           | 01 Sep 2020 23:03:16 |
|  | System           | 01 Sep 2020 23:03:16 |

US3802074

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:55:48

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:48 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-09-01T19:03:09', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '0a7e1bd1-04a0-48d9-9504-464e68dda8f4' User entered 'No (N)' | System           | 01 Sep 2020 23:03:16 |
|  | System           | 01 Sep 2020 23:03:16 |

**US3802074**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:55:48**

[PC Time stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 06 Mar 2021 23:14:48 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-09-01T19:03:15', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '0a7e1bd1-04a0-48d9-9504-464e68dda8f4' User entered '01 Sep 2020 19:03' | System           | 01 Sep 2020 23:03:16 |
|   | System           | 01 Sep 2020 23:03:16 |

**US3802074**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:55:48**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:14:48 |
| User entered '01 Sep 2020 12:00' | System           | 31 Aug 2020 13:54:40 |



**US3802074**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:55:48**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:14:48 |
| User entered '02 Sep 2020 11:59' | System           | 31 Aug 2020 13:54:40 |

US3802074

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:55:48

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 06 Mar 2021 23:14:48 |
| Data entry locked.   | System           | 31 Aug 2020 13:54:40 |
| User entered 'Day 3' | System           | 31 Aug 2020 13:54:40 |

US3802074

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:55:48

**HEADACHE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:48 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-09-02T22:10:13', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '0cfc4cba-deb7-4a26-8c1e-0d0d9425ad4c' User entered 'None (0)' | System           | 03 Sep 2020 02:10:38 |
|  | System           | 03 Sep 2020 02:10:38 |

US3802074

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:55:48

**FATIGUE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:48 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-09-02T22:10:17', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '0cfc4cba-deb7-4a26-8c1e-0d0d9425ad4c' | System           | 03 Sep 2020 02:10:38 |
| User entered 'No interference with activity (1)'   | System           | 03 Sep 2020 02:10:38 |

US3802074

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:55:48

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:48 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-09-02T22:10:20', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '0cfc4cba-deb7-4a26-8c1e-0d0d9425ad4c' User entered 'None (0)' | System           | 03 Sep 2020 02:10:38 |
|  | System           | 03 Sep 2020 02:10:38 |

US3802074

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:55:48

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:48 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-09-02T22:10:22', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '0cfc4cba-deb7-4a26-8c1e-0d0d9425ad4c' User entered 'None (0)' | System           | 03 Sep 2020 02:10:38 |
|  | System           | 03 Sep 2020 02:10:38 |

US3802074

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:55:48

**NAUSEA/VOMITING**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:48 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-09-02T22:10:25', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '0cfc4cba-deb7-4a26-8c1e-0d0d9425ad4c' User entered 'None (0)' | System           | 03 Sep 2020 02:10:38 |
|  | System           | 03 Sep 2020 02:10:38 |

US3802074

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:55:48

**CHILLS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:48 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-09-02T22:10:27', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '0cfc4cba-deb7-4a26-8c1e-0d0d9425ad4c' User entered 'None (0)' | System           | 03 Sep 2020 02:10:38 |
|  | System           | 03 Sep 2020 02:10:38 |



US3802074

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:55:48

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:48 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-09-02T22:10:31', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '0cfc4cba-deb7-4a26-8c1e-0d0d9425ad4c' User entered 'No (N)' | System           | 03 Sep 2020 02:10:38 |
|  | System           | 03 Sep 2020 02:10:38 |

**US3802074**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:55:48**

[PC Time stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 06 Mar 2021 23:14:48 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-09-02T22:10:36', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '0cfc4cba-deb7-4a26-8c1e-0d0d9425ad4c' User entered '02 Sep 2020 22:10' | System           | 03 Sep 2020 02:10:38 |
|   | System           | 03 Sep 2020 02:10:38 |

**US3802074**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:55:48**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:14:48 |
| User entered '02 Sep 2020 12:00' | System           | 31 Aug 2020 13:54:40 |

**US3802074**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:55:48**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:14:48 |
| User entered '03 Sep 2020 11:59' | System           | 31 Aug 2020 13:54:40 |

**US3802074**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:55:48**

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 06 Mar 2021 23:14:48 |
| Data entry locked.   | System           | 31 Aug 2020 13:54:40 |
| User entered 'Day 4' | System           | 31 Aug 2020 13:54:40 |

US3802074

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:55:48

**HEADACHE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:48 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-09-03T18:43:08', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '9fac407f-e3cc-40f2-a47d-473efc72076d' User entered 'None (0)' | System           | 03 Sep 2020 22:43:29 |
|  | System           | 03 Sep 2020 22:43:29 |

US3802074

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:55:48

**FATIGUE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:48 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-09-03T18:43:09', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '9fac407f-e3cc-40f2-a47d-473efc72076d' User entered 'None (0)' | System           | 03 Sep 2020 22:43:29 |
|  | System           | 03 Sep 2020 22:43:29 |

US3802074

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:55:48

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:48 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-09-03T18:43:11', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '9fac407f-e3cc-40f2-a47d-473efc72076d' User entered 'None (0)' | System           | 03 Sep 2020 22:43:29 |
|  | System           | 03 Sep 2020 22:43:29 |



US3802074

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:55:48

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:48 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-09-03T18:43:13', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '9fac407f-e3cc-40f2-a47d-473efc72076d' User entered 'None (0)' | System           | 03 Sep 2020 22:43:29 |
|  | System           | 03 Sep 2020 22:43:29 |

**US3802074**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:55:48**

**NAUSEA/VOMITING**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:48 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-09-03T18:43:17', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '9fac407f-e3cc-40f2-a47d-473efc72076d' User entered 'None (0)' | System           | 03 Sep 2020 22:43:29 |
|  | System           | 03 Sep 2020 22:43:29 |

**US3802074**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:55:48**

**CHILLS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:48 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-09-03T18:43:19', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '9fac407f-e3cc-40f2-a47d-473efc72076d' User entered 'None (0)' | System           | 03 Sep 2020 22:43:29 |
|  | System           | 03 Sep 2020 22:43:29 |

US3802074

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:55:48

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:48 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-09-03T18:43:23', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '9fac407f-e3cc-40f2-a47d-473efc72076d' User entered 'No (N)' | System           | 03 Sep 2020 22:43:29 |
|  | System           | 03 Sep 2020 22:43:29 |

**US3802074**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:55:48**

[PC Time stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 06 Mar 2021 23:14:48 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-09-03T18:43:26', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '9fac407f-e3cc-40f2-a47d-473efc72076d' User entered '03 Sep 2020 18:43' | System           | 03 Sep 2020 22:43:29 |
|   | System           | 03 Sep 2020 22:43:29 |

**US3802074**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:55:48**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:14:48 |
| User entered '03 Sep 2020 12:00' | System           | 31 Aug 2020 13:54:40 |

**US3802074**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:55:48**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:14:48 |
| User entered '04 Sep 2020 11:59' | System           | 31 Aug 2020 13:54:40 |

**US3802074**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:55:48**

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 06 Mar 2021 23:14:48 |
| Data entry locked.   | System           | 31 Aug 2020 13:54:40 |
| User entered 'Day 5' | System           | 31 Aug 2020 13:54:40 |



**US3802074**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:55:48**

**HEADACHE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:48 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-09-04T19:37:18', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '6441d224-9090-4496-8407-3e82918a0dae' User entered 'None (0)' | System           | 04 Sep 2020 23:37:38 |
|  | System           | 04 Sep 2020 23:37:38 |

US3802074

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:55:48

**FATIGUE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:48 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-09-04T19:37:21', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '6441d224-9090-4496-8407-3e82918a0dae' User entered 'None (0)' | System           | 04 Sep 2020 23:37:38 |
|  | System           | 04 Sep 2020 23:37:38 |

US3802074

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:55:48

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:48 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-09-04T19:37:23', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '6441d224-9090-4496-8407-3e82918a0dae' User entered 'None (0)' | System           | 04 Sep 2020 23:37:38 |
|  | System           | 04 Sep 2020 23:37:38 |

US3802074

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:55:48

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:48 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-09-04T19:37:25', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '6441d224-9090-4496-8407-3e82918a0dae' User entered 'None (0)' | System           | 04 Sep 2020 23:37:38 |
|  | System           | 04 Sep 2020 23:37:38 |

**US3802074**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:55:48**

**NAUSEA/VOMITING**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:48 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-09-04T19:37:27', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '6441d224-9090-4496-8407-3e82918a0dae' User entered 'None (0)' | System           | 04 Sep 2020 23:37:38 |
|  | System           | 04 Sep 2020 23:37:38 |

**US3802074**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:55:48**

**CHILLS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:48 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-09-04T19:37:30', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '6441d224-9090-4496-8407-3e82918a0dae' User entered 'None (0)' | System           | 04 Sep 2020 23:37:38 |
|  | System           | 04 Sep 2020 23:37:38 |

US3802074

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:55:48

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:48 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-09-04T19:37:34', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '6441d224-9090-4496-8407-3e82918a0dae' User entered 'No (N)' | System           | 04 Sep 2020 23:37:38 |
|  | System           | 04 Sep 2020 23:37:38 |

**US3802074**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:55:48**

[PC Time stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 06 Mar 2021 23:14:48 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-09-04T19:37:36', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '6441d224-9090-4496-8407-3e82918a0dae' User entered '04 Sep 2020 19:37' | System           | 04 Sep 2020 23:37:38 |
|   | System           | 04 Sep 2020 23:37:38 |



**US3802074**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:55:48**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:14:48 |
| User entered '04 Sep 2020 12:00' | System           | 31 Aug 2020 13:54:40 |

**US3802074**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:55:48**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:14:48 |
| User entered '05 Sep 2020 11:59' | System           | 31 Aug 2020 13:54:40 |

**US3802074**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:55:48**

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 06 Mar 2021 23:14:48 |
| Data entry locked.   | System           | 31 Aug 2020 13:54:40 |
| User entered 'Day 6' | System           | 31 Aug 2020 13:54:40 |

**US3802074**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:55:48**

**HEADACHE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:48 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-09-05T18:45:32', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '1d4316a7-eb4f-41c0-834f-4bb864b0c586' | System           | 05 Sep 2020 22:45:59 |
| User entered 'None (0)'  | System           | 05 Sep 2020 22:45:59 |

**US3802074**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:55:48**

**FATIGUE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:48 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-09-05T18:45:34', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '1d4316a7-eb4f-41c0-834f-4bb864b0c586' | System           | 05 Sep 2020 22:45:59 |
| User entered 'None (0)'  | System           | 05 Sep 2020 22:45:59 |

US3802074

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:55:48

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:48 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-09-05T18:45:36', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '1d4316a7-eb4f-41c0-834f-4bb864b0c586' | System           | 05 Sep 2020 22:45:59 |
| User entered 'None (0)'  | System           | 05 Sep 2020 22:45:59 |

**US3802074**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:55:48**

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:48 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-09-05T18:45:39', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '1d4316a7-eb4f-41c0-834f-4bb864b0c586' User entered 'None (0)' | System           | 05 Sep 2020 22:45:59 |
|  | System           | 05 Sep 2020 22:45:59 |

**US3802074**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:55:48**

**NAUSEA/VOMITING**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:48 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-09-05T18:45:46', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '1d4316a7-eb4f-41c0-834f-4bb864b0c586' User entered 'None (0)' | System           | 05 Sep 2020 22:45:59 |
|  | System           | 05 Sep 2020 22:45:59 |



**US3802074**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:55:48**

**CHILLS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:48 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-09-05T18:45:49', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '1d4316a7-eb4f-41c0-834f-4bb864b0c586' User entered 'None (0)' | System           | 05 Sep 2020 22:45:59 |
|  | System           | 05 Sep 2020 22:45:59 |

US3802074

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:55:48

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:48 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-09-05T18:45:52', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '1d4316a7-eb4f-41c0-834f-4bb864b0c586' | System           | 05 Sep 2020 22:45:59 |
| User entered 'No (N)'  | System           | 05 Sep 2020 22:45:59 |

**US3802074**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:55:48**

[PC Time stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 06 Mar 2021 23:14:48 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-09-05T18:45:55', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '1d4316a7-eb4f-41c0-834f-4bb864b0c586' User entered '05 Sep 2020 18:45' | System           | 05 Sep 2020 22:45:59 |
|   | System           | 05 Sep 2020 22:45:59 |

**US3802074**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:55:48**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:14:48 |
| User entered '05 Sep 2020 12:00' | System           | 31 Aug 2020 13:54:40 |

**US3802074**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:55:48**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:14:48 |
| User entered '06 Sep 2020 11:59' | System           | 31 Aug 2020 13:54:40 |

**US3802074**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:55:48**

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 06 Mar 2021 23:14:48 |
| Data entry locked.   | System           | 31 Aug 2020 13:54:40 |
| User entered 'Day 7' | System           | 31 Aug 2020 13:54:40 |

US3802074

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:55:48

**HEADACHE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:48 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-09-06T18:42:45', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '46ac0458-e491-4538-8fed-b794d97031c9' | System           | 06 Sep 2020 22:43:33 |
| User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'  | System           | 06 Sep 2020 22:43:33 |

**US3802074**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:55:48**

**FATIGUE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:48 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-09-06T18:42:48', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '46ac0458-e491-4538-8fed-b794d97031c9' | System           | 06 Sep 2020 22:43:33 |
| User entered 'Some interference with activity (2)'   | System           | 06 Sep 2020 22:43:33 |



US3802074

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:55:48

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:48 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-09-06T18:42:55', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '46ac0458-e491-4538-8fed-b794d97031c9' | System           | 06 Sep 2020 22:43:33 |
| User entered 'Some interference with activity (2)'   | System           | 06 Sep 2020 22:43:33 |

US3802074

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:55:48

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:48 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-09-06T18:43:05', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '46ac0458-e491-4538-8fed-b794d97031c9' | System           | 06 Sep 2020 22:43:33 |
| User entered 'No interference with activity (1)'   | System           | 06 Sep 2020 22:43:33 |

**US3802074**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:55:48**

**NAUSEA/VOMITING**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:48 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-09-06T18:43:08', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '46ac0458-e491-4538-8fed-b794d97031c9' User entered 'None (0)' | System           | 06 Sep 2020 22:43:33 |
|  | System           | 06 Sep 2020 22:43:33 |

**US3802074**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:55:48**

**CHILLS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:48 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-09-06T18:43:10', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '46ac0458-e491-4538-8fed-b794d97031c9' User entered 'None (0)' | System           | 06 Sep 2020 22:43:33 |
|  | System           | 06 Sep 2020 22:43:33 |

US3802074

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:55:48

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:48 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-09-06T18:43:14', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '46ac0458-e491-4538-8fed-b794d97031c9' User entered 'No (N)' | System           | 06 Sep 2020 22:43:33 |
|  | System           | 06 Sep 2020 22:43:33 |

**US3802074**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:55:48**

[PC Time stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 06 Mar 2021 23:14:48 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-09-06T18:43:30', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '46ac0458-e491-4538-8fed-b794d97031c9' User entered '06 Sep 2020 18:43' | System           | 06 Sep 2020 22:43:33 |
|   | System           | 06 Sep 2020 22:43:33 |

**US3802074**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:55:48**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:14:48 |
| User entered '06 Sep 2020 12:00' | System           | 31 Aug 2020 13:54:40 |

**US3802074**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:55:48**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:14:48 |
| User entered '07 Sep 2020 11:59' | System           | 31 Aug 2020 13:54:40 |



US3802074

Folder: Diary Dose 1 (1)

Form: Headache\_Day(8)

Generated On: 10 Jun 2021 09:55:48

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 06 Mar 2021 23:14:48 |
| Data entry locked.   | System           | 06 Sep 2020 22:43:33 |
| User entered 'Day 8' | System           | 06 Sep 2020 22:43:33 |

US3802074

Folder: Diary Dose 1 (1)

Form: Headache\_Day(8)

Generated On: 10 Jun 2021 09:55:48

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:48 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-09-07T17:30:03', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '63090e36-7210-47c6-bccf-8f6a89d71c4c' User entered 'None (0)' | System           | 07 Sep 2020 21:30:10 |
|  | System           | 07 Sep 2020 21:30:10 |

**US3802074**

**Folder: Diary Dose 1 (1)**

**Form: Headache\_Day(8)**

**Generated On: 10 Jun 2021 09:55:48**

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 06 Mar 2021 23:14:48 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-09-07T17:30:08', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '63090e36-7210-47c6-bccf-8f6a89d71c4c' User entered '07 Sep 2020 17:30' | System           | 07 Sep 2020 21:30:10 |
|   | System           | 07 Sep 2020 21:30:10 |

**US3802074**

**Folder: Diary Dose 1 (1)**

**Form: Headache\_Day(8)**

**Generated On: 10 Jun 2021 09:55:48**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:14:48 |
| User entered '07 Sep 2020 12:00' | System           | 06 Sep 2020 22:43:33 |

US3802074

Folder: Diary Dose 1 (1)

Form: Headache\_Day(8)

Generated On: 10 Jun 2021 09:55:48

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:14:48 |
| User entered '08 Sep 2020 11:59' | System           | 06 Sep 2020 22:43:33 |

**US3802074**

**Folder: Diary Dose 1 (1)**

**Form: Fatigue\_Day(8)**

**Generated On: 10 Jun 2021 09:55:48**

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 06 Mar 2021 23:14:48 |
| Data entry locked.   | System           | 06 Sep 2020 22:43:33 |
| User entered 'Day 8' | System           | 06 Sep 2020 22:43:33 |

**US3802074**

**Folder: Diary Dose 1 (1)**

**Form: Fatigue\_Day(8)**

**Generated On: 10 Jun 2021 09:55:48**

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:48 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-09-07T17:30:12', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: 'aef85e34-267c-43e0-bd33-05ed3ff4eb33' | System           | 07 Sep 2020 21:30:17 |
| User entered 'None (0)'  | System           | 07 Sep 2020 21:30:17 |

**US3802074**

**Folder: Diary Dose 1 (1)**

**Form: Fatigue\_Day(8)**

**Generated On: 10 Jun 2021 09:55:48**

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:48 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-09-07T17:30:15', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: 'aef85e34-267c-43e0-bd33-05ed3ff4eb33' | System           | 07 Sep 2020 21:30:17 |
| User entered '07 Sep 2020 17:30'   | System           | 07 Sep 2020 21:30:17 |



**US3802074**

**Folder: Diary Dose 1 (1)**

**Form: Fatigue\_Day(8)**

**Generated On: 10 Jun 2021 09:55:48**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:14:48 |
| User entered '07 Sep 2020 12:00' | System           | 06 Sep 2020 22:43:33 |

**US3802074**

**Folder: Diary Dose 1 (1)**

**Form: Fatigue\_Day(8)**

**Generated On: 10 Jun 2021 09:55:48**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:14:48 |
| User entered '08 Sep 2020 11:59' | System           | 06 Sep 2020 22:43:33 |

**US3802074**

**Folder: Diary Dose 1 (1)**

**Form: MuscleAche\_Day(8)**

**Generated On: 10 Jun 2021 09:55:48**

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| Data entry locked.   | System           | 06 Sep 2020 22:43:33 |
| User entered 'Day 8' | System           | 06 Sep 2020 22:43:33 |

US3802074

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(8)

Generated On: 10 Jun 2021 09:55:48

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-09-07T17:30:19', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '7ff49fd6-f055-40dc-9355-03e565792e1c' User entered 'None (0)' | System           | 07 Sep 2020 21:30:24 |
|  | System           | 07 Sep 2020 21:30:24 |

**US3802074**

**Folder: Diary Dose 1 (1)**

**Form: MuscleAche\_Day(8)**

**Generated On: 10 Jun 2021 09:55:48**

[PC Time stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-09-07T17:30:22', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '7ff49fd6-f055-40dc-9355-03e565792e1c' User entered '07 Sep 2020 17:30' | System           | 07 Sep 2020 21:30:24 |
|   | System           | 07 Sep 2020 21:30:24 |

**US3802074**

**Folder: Diary Dose 1 (1)**

**Form: MuscleAche\_Day(8)**

**Generated On: 10 Jun 2021 09:55:48**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| User entered '07 Sep 2020 12:00' | System           | 06 Sep 2020 22:43:33 |

**US3802074**

**Folder: Diary Dose 1 (1)**

**Form: MuscleAche\_Day(8)**

**Generated On: 10 Jun 2021 09:55:48**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| User entered '08 Sep 2020 11:59' | System           | 06 Sep 2020 22:43:33 |

**US3802074**

**Folder: Diary Dose 1 (1)**

**Form: JointsAche\_Day(8)**

**Generated On: 10 Jun 2021 09:55:48**

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| Data entry locked.   | System           | 06 Sep 2020 22:43:33 |
| User entered 'Day 8' | System           | 06 Sep 2020 22:43:33 |



US3802074

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(8)

Generated On: 10 Jun 2021 09:55:48

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-09-07T17:30:26', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '6963dc98-2cd7-4e42-8016-d4881dbe015e' User entered 'None (0)' | System           | 07 Sep 2020 21:30:30 |
|  | System           | 07 Sep 2020 21:30:30 |

**US3802074**

**Folder: Diary Dose 1 (1)**

**Form: JointsAche\_Day(8)**

**Generated On: 10 Jun 2021 09:55:48**

[PC Time stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-09-07T17:30:28', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '6963dc98-2cd7-4e42-8016-d4881dbe015e' User entered '07 Sep 2020 17:30' | System           | 07 Sep 2020 21:30:30 |
|   | System           | 07 Sep 2020 21:30:30 |

**US3802074**

**Folder: Diary Dose 1 (1)**

**Form: JointsAche\_Day(8)**

**Generated On: 10 Jun 2021 09:55:48**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| User entered '07 Sep 2020 12:00' | System           | 06 Sep 2020 22:43:33 |

**US3802074**

**Folder: Diary Dose 1 (1)**

**Form: JointsAche\_Day(8)**

**Generated On: 10 Jun 2021 09:55:48**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| User entered '08 Sep 2020 11:59' | System           | 06 Sep 2020 22:43:33 |

**US3802074**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(8)**

**Generated On: 10 Jun 2021 09:55:48**

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| Data entry locked.   | System           | 06 Sep 2020 22:42:22 |
| User entered 'Day 8' | System           | 06 Sep 2020 22:42:22 |

US3802074

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 10 Jun 2021 09:55:48

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-09-07T17:30:35', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: 'b02aa53f-8526-44b3-89d7-4265af13d922' | System           | 07 Sep 2020 21:30:41 |
| User entered 'No (N)'  | System           | 07 Sep 2020 21:30:41 |

**US3802074**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(8)**

**Generated On: 10 Jun 2021 09:55:48**

[PC Time stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-09-07T17:30:38', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: 'b02aa53f-8526-44b3-89d7-4265af13d922' | System           | 07 Sep 2020 21:30:41 |
| User entered '07 Sep 2020 17:30'   | System           | 07 Sep 2020 21:30:41 |

**US3802074**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(8)**

**Generated On: 10 Jun 2021 09:55:48**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| User entered '07 Sep 2020 12:00' | System           | 06 Sep 2020 22:42:22 |



**US3802074**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(8)**

**Generated On: 10 Jun 2021 09:55:48**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| User entered '08 Sep 2020 11:59' | System           | 06 Sep 2020 22:42:22 |

**US3802074**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:55:48**

[Was Contact Attempted?](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 28 Apr 2021 11:19:23 |
| DataPoint Verified.       |                       | 07 Oct 2020 18:36:17 |
| User signature succeeded. | Judith Martin (b) (4) | 07 Sep 2020 19:27:15 |
| User entered 'Yes (Y)'    | (b) (4)               |                      |
|                           | Judith Martin (b) (4) | 07 Sep 2020 19:27:07 |
|                           | (b) (4)               |                      |

**US3802074**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:55:48**

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

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 28 Apr 2021 11:19:23 |
| DataPoint Verified.       |                       | 07 Oct 2020 18:36:17 |
| User signature succeeded. | Judith Martin (b) (4) | 07 Sep 2020 19:27:15 |
| User entered '7 Sep 2020' | (b) (4)               |                      |
|                           | Judith Martin (b) (4) | 07 Sep 2020 19:27:07 |
|                           | (b) (4)               |                      |

**US3802074**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:55:48**

[Please select one status for the follow-up contact](#)

| Audit                                      | User                  | Time (GMT)           |
|--|-----------------------|----------------------|
| Data hard locked.                          | (b) (4), (b) (6)      | 28 Apr 2021 11:19:23 |
| DataPoint Verified.                        |                       | 07 Oct 2020 18:36:17 |
| User signature succeeded.                  | Judith Martin (b) (4) | 07 Sep 2020 19:27:15 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4)               |                      |
|  | Judith Martin (b) (4) | 07 Sep 2020 19:27:07 |
|  | (b) (4)               |                      |

**US3802074**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:55:48**

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 28 Apr 2021 11:19:23 |
| DataPoint Verified.       |                       | 07 Oct 2020 18:36:17 |
| User signature succeeded. | Judith Martin (b) (4) | 07 Sep 2020 19:27:15 |
| User entered empty.       | (b) (4)               |                      |
|                           | Judith Martin (b) (4) | 07 Sep 2020 19:27:07 |
|                           | (b) (4)               |                      |

**US3802074**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:55:48**

[Is the participant continuing to the next visit?](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 28 Apr 2021 11:19:23 |
| DataPoint Verified.       |                       | 07 Oct 2020 18:36:24 |
| User signature succeeded. | Judith Martin (b) (4) | 07 Sep 2020 19:27:41 |
| User entered 'Yes (Y)'    | (b) (4)               |                      |
|                           | Judith Martin (b) (4) | 07 Sep 2020 19:27:35 |
|                           | (b) (4)               |                      |

**US3802074**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:55:48**

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 11:19:23 |
| User entered 'I'  | System           | 07 Sep 2020 19:27:35 |

**US3802074**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:55:48**

[Was Contact Attempted?](#)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 28 Apr 2021 11:19:23 |
| User signature succeeded. | Judith Martin (b) (4)            | 28 Jan 2021 18:19:31 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)      | 07 Oct 2020 18:37:46 |
| User entered 'Yes (Y)'    | Jennifer Nagg (b) (4)<br>(b) (4) | 16 Sep 2020 20:15:39 |



**US3802074**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:55:48**

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

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                 | 28 Apr 2021 11:19:23 |
| User signature succeeded.  | Judith Martin (b) (4)            | 28 Jan 2021 18:19:31 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6)      | 07 Oct 2020 18:37:46 |
| User entered '16 Sep 2020' | Jennifer Nagg (b) (4)<br>(b) (4) | 16 Sep 2020 20:15:39 |

US3802074

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:55:48

[Please select one status for the follow-up contact](#)

| Audit                                      | User                             | Time (GMT)           |
|--|----------------------------------|----------------------|
| Data hard locked.                          | (b) (4), (b) (6)                 | 28 Apr 2021 11:19:23 |
| User signature succeeded.                  | Judith Martin (b) (4)            | 28 Jan 2021 18:19:31 |
| DataPoint Verified.                        | (b) (4)<br>(u) (4), (b) (6)      | 07 Oct 2020 18:37:46 |
| User entered 'Contact Made (CONTACT MADE)' | Jennifer Nagg (b) (4)<br>(b) (4) | 16 Sep 2020 20:15:39 |

US3802074

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:55:48

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 28 Apr 2021 11:19:23 |
| User signature succeeded. | Judith Martin (b) (4)            | 28 Jan 2021 18:19:31 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)      | 07 Oct 2020 18:37:46 |
| User entered empty.       | Jennifer Nagg (b) (4)<br>(b) (4) | 16 Sep 2020 20:15:39 |

US3802074

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:55:48

[Is the participant continuing to the next visit?](#)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 28 Apr 2021 11:19:23 |
| User signature succeeded. | Judith Martin (b) (4)<br>(b) (4) | 28 Jan 2021 18:19:31 |
| DataPoint Verified.       | (b) (4), (b) (6)                 | 07 Oct 2020 18:37:53 |
| User entered 'Yes (Y)'    | Jennifer Nagg (b) (4)<br>(b) (4) | 16 Sep 2020 20:15:46 |

**US3802074**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:55:48**

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 11:19:23 |
| User entered 'I'  | System           | 16 Sep 2020 20:15:46 |

**US3802074**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:55:48**

[Was Contact Attempted?](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 28 Apr 2021 11:19:23 |
| User signature succeeded. | Judith Martin (b) (4)             | 28 Jan 2021 18:19:31 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 07 Oct 2020 18:38:25 |
| User entered 'Yes (Y)'    | Dominic Kramer (b) (4)<br>(b) (4) | 21 Sep 2020 17:28:08 |

**US3802074**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:55:48**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

| Audit                      | User                   | Time (GMT)           |
|----------------------------|------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)       | 28 Apr 2021 11:19:23 |
| User signature succeeded.  | Judith Martin (b) (4)  | 28 Jan 2021 18:19:31 |
| DataPoint Verified.        | (b) (4), (b) (6)       | 07 Oct 2020 18:38:25 |
| User entered '21 Sep 2020' | Dominic Kramer (b) (4) | 21 Sep 2020 17:28:08 |

**US3802074**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:55:48**

[Please select one status for the follow-up contact](#)

| Audit                                      | User                   | Time (GMT)           |
|--|------------------------|----------------------|
| Data hard locked.                          | (b) (4), (b) (6)       | 28 Apr 2021 11:19:23 |
| User signature succeeded.                  | Judith Martin (b) (4)  | 28 Jan 2021 18:19:31 |
| DataPoint Verified.                        | (b) (4), (b) (6)       | 07 Oct 2020 18:38:25 |
| User entered 'Contact Made (CONTACT MADE)' | Dominic Kramer (b) (4) | 21 Sep 2020 17:28:08 |



**US3802074**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:55:48**

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 11:19:23 |
| User signature succeeded. | Judith Martin (b) (4)  | 28 Jan 2021 18:19:31 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 07 Oct 2020 18:38:25 |
| User entered empty.       | Dominic Kramer (b) (4) | 21 Sep 2020 17:28:08 |

US3802074

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:55:48

[Is the participant continuing to the next visit?](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 11:19:23 |
| User signature succeeded. | Judith Martin (b) (4)  | 28 Jan 2021 18:19:31 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 07 Oct 2020 18:38:35 |
| User entered 'Yes (Y)'    | Dominic Kramer (b) (4) | 21 Sep 2020 17:28:14 |

**US3802074**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:55:48**

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 11:19:23 |
| User entered 'I'  | System           | 21 Sep 2020 17:28:14 |

US3802074

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:55:48

[Was this visit performed?](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 29 Apr 2021 15:42:08 |
| User signature succeeded. | Judith Martin (b) (4) | 28 Jan 2021 18:19:31 |
| DataPoint Verified.       | (b) (4), (b) (6)      | 07 Oct 2020 18:24:41 |
| User entered 'Yes (Y)'    | Emily Carney (b) (4)  | 28 Sep 2020 13:25:31 |

US3802074

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:55:48

Visit date (dd MMM yyyy)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 29 Apr 2021 15:42:08 |
| User signature succeeded.  | Judith Martin (b) (4) | 28 Jan 2021 18:19:31 |
| DataPoint Verified.        | (b) (4), (b) (6)      | 07 Oct 2020 18:24:41 |
| User entered '28 Sep 2020' | Emily Carney (b) (4)  | 28 Sep 2020 13:25:31 |

US3802074

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:55:48

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

| Audit                          | User                  | Time (GMT)           |
|--------------------------------|-----------------------|----------------------|
| Data hard locked.              | (b) (4), (b) (6)      | 29 Apr 2021 15:42:08 |
| User signature succeeded.      | Judith Martin (b) (4) | 28 Jan 2021 18:19:31 |
| DataPoint Verified.            | (b) (4), (b) (6)      | 07 Oct 2020 18:24:41 |
| User entered 'Clinic (Clinic)' | Emily Carney (b) (4)  | 28 Sep 2020 13:25:31 |

**US3802074**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:55:48**

[Folder OID](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| Data hard locked.     | (b) (4), (b) (6) | 29 Apr 2021 15:42:08 |
| User entered 'VISIT2' | System           | 28 Sep 2020 13:25:31 |

US3802074

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:55:48

[Timepoint](#)

| Audit  | User                            | Time (GMT)           |
|--|---------------------------------|----------------------|
| Data hard locked.                                | (b) (4), (b) (6)                | 29 Apr 2021 15:42:08 |
| User accepted default value 'Pre-Dose (PREDOSE)' | Emily Carney (b) (4)<br>(b) (4) | 28 Sep 2020 14:11:47 |



US3802074

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:55:48

[Were vital signs assessed?](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 29 Apr 2021 15:42:08 |
| User signature succeeded. | Judith Martin (b) (4) | 28 Jan 2021 18:19:31 |
| DataPoint Verified.       | (b) (4), (b) (6)      | 07 Oct 2020 18:25:18 |
| User entered 'Yes (Y)'    | Emily Carney (b) (4)  | 28 Sep 2020 14:11:47 |

US3802074

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:55:48

Date of assessment (*dd MMM yyyy*)

| Audit                      | User                            | Time (GMT)           |
|----------------------------|---------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                | 29 Apr 2021 15:42:08 |
| User signature succeeded.  | Judith Martin (b) (4)           | 28 Jan 2021 18:19:31 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6)     | 07 Oct 2020 18:25:28 |
| User entered '28 Sep 2020' | Emily Carney (b) (4)<br>(b) (4) | 28 Sep 2020 14:11:47 |

**US3802074**

**Folder: Visit 2 Day 29 (1)**

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

**Generated On: 10 Jun 2021 09:55:48**

**Time of assessment (00:00-23:59)**

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 29 Apr 2021 15:42:08 |
| User signature succeeded. | Judith Martin (b) (4) | 28 Jan 2021 18:19:31 |
| DataPoint Verified.       | (b) (4), (b) (6)      | 07 Oct 2020 18:25:29 |
| User entered '09:05'      | Emily Carney (b) (4)  | 28 Sep 2020 14:11:47 |

**US3802074**

**Folder: Visit 2 Day 29 (1)**

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

**Generated On: 10 Jun 2021 09:55:48**

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

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 29 Apr 2021 15:42:08 |
| User entered '28 Sep 2020 09:05' | System           | 28 Sep 2020 14:11:47 |

US3802074

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:55:48

Temperature (xxx.x)

| Audit  | User                            | Time (GMT)           |
|--|---------------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)                | 29 Apr 2021 15:42:08 |
| DataPoint Verified.  |                                 | 23 Apr 2021 14:01:44 |
| User signature succeeded.  | Judith Martin (b) (4)           | 28 Jan 2021 18:19:31 |
| User closed query 'Per CDM: Site response noted; however, please confirm if CS or NCS and report AE if appropriate. Thank you. ' (Site from DM).   | (b) (4)<br>(b) (4), (b) (6)     | 13 Oct 2020 07:55:29 |
| Query 'Per CDM: Site response noted; however, please confirm if CS or NCS and report AE if appropriate. Thank you. ' answered with 'NCS' (Site from DM).   | Melissa Andrasko (b) (4)        | 06 Oct 2020 15:18:32 |
| User opened query 'Per CDM: Site response noted; however, please confirm if CS or NCS and report AE if appropriate. Thank you. ' (Site from DM).   | (b) (4), (b) (6)                | 29 Sep 2020 12:31:06 |
| User closed query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3 Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).                        |                                 | 29 Sep 2020 12:30:59 |
| Query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'Correct infrared ' (Site from System). | Emily Carney (b) (4)<br>(b) (4) | 28 Sep 2020 14:11:58 |
| User opened query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).                       | System                          | 28 Sep 2020 14:11:47 |
| User entered '96.3' F  | Emily Carney (b) (4)<br>(b) (4) | 28 Sep 2020 14:11:47 |

US3802074

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:55:48

[Route of measurement](#)

| Audit                        | User                  | Time (GMT)           |
|------------------------------|-----------------------|----------------------|
| Data hard locked.            | (b) (4), (b) (6)      | 29 Apr 2021 15:42:08 |
|                              |                       |                      |
|                              |                       |                      |
| User signature succeeded.    | Judith Martin (b) (4) | 28 Jan 2021 18:19:31 |
|                              | (b) (4)               |                      |
| DataPoint Verified.          | (b) (4), (b) (6)      | 07 Oct 2020 18:25:39 |
|                              |                       |                      |
| User entered 'Other (Other)' | Emily Carney (b) (4)  | 28 Sep 2020 14:11:47 |
|                              | (b) (4)               |                      |

US3802074

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:55:48

[If Other, specify](#)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                | 29 Apr 2021 15:42:08 |
| User signature succeeded. | Judith Martin (b) (4)           | 28 Jan 2021 18:19:31 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)     | 07 Oct 2020 18:25:40 |
| User entered 'Infrared'   | Emily Carney (b) (4)<br>(b) (4) | 28 Sep 2020 14:11:47 |

US3802074

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:55:48

[Pulse \(xxx\)](#)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                | 29 Apr 2021 15:42:08 |
| User signature succeeded. | Judith Martin (b) (4)           | 28 Jan 2021 18:19:31 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)     | 07 Oct 2020 18:25:44 |
| User entered '66'         | Emily Carney (b) (4)<br>(b) (4) | 28 Sep 2020 14:11:47 |



**US3802074**

**Folder: Visit 2 Day 29 (1)**

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

**Generated On: 10 Jun 2021 09:55:48**

[Pulse units](#)

| Audit              | User             | Time (GMT)           |
|--------------------|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 29 Apr 2021 15:42:08 |
| User entered 'bpm' | System           | 28 Sep 2020 14:11:47 |

US3802074

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:55:48

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

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                | 29 Apr 2021 15:42:08 |
| User signature succeeded. | Judith Martin (b) (4)           | 28 Jan 2021 18:19:31 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)     | 07 Oct 2020 18:26:26 |
| User entered '18'         | Emily Carney (b) (4)<br>(b) (4) | 28 Sep 2020 14:11:47 |

US3802074

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:55:48

[Respiratory Rate units](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6) | 29 Apr 2021 15:42:08 |
| User entered 'breaths/min' | System           | 28 Sep 2020 14:11:47 |

US3802074

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:55:48

Systolic Blood Pressure (xxx)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                | 29 Apr 2021 15:42:08 |
| User signature succeeded. | Judith Martin (b) (4)           | 28 Jan 2021 18:19:31 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)     | 07 Oct 2020 18:26:22 |
| User entered '153'        | Emily Carney (b) (4)<br>(b) (4) | 28 Sep 2020 14:11:47 |

US3802074

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:55:48

[Systolic Blood Pressure units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 29 Apr 2021 15:42:08 |
|                     |                  |                      |
|                     |                  |                      |
| User entered 'mmHg' | System           | 28 Sep 2020 14:11:47 |

US3802074

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:55:48

Diastolic Blood Pressure (xxx)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                | 29 Apr 2021 15:42:08 |
| User signature succeeded. | Judith Martin (b) (4)           | 28 Jan 2021 18:19:31 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)     | 07 Oct 2020 18:26:21 |
| User entered '92'         | Emily Carney (b) (4)<br>(b) (4) | 28 Sep 2020 14:11:47 |

US3802074

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:55:48

Diastolic Blood Pressure units

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 29 Apr 2021 15:42:08 |
| User entered 'mmHg' | System           | 28 Sep 2020 14:11:47 |

US3802074

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:55:48

[Timepoint](#)

| Audit  | User                 | Time (GMT)           |
|--|----------------------|----------------------|
| Data hard locked.                                  | (b) (4), (b) (6)     | 29 Apr 2021 15:42:08 |
|  |                      |                      |
|  |                      |                      |
|  |                      |                      |
| User accepted default value 'Post-Dose (POSTDOSE)' | Emily Carney (b) (4) | 28 Sep 2020 14:11:47 |
|  | (b) (4)              |                      |



US3802074

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:55:48

[Were vital signs assessed?](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 29 Apr 2021 15:42:08 |
|                           |                       |                      |
|                           |                       |                      |
| User signature succeeded. | Judith Martin (b) (4) | 28 Jan 2021 18:19:31 |
|                           | (b) (4)               |                      |
| DataPoint Verified.       | (b) (4), (b) (6)      | 07 Oct 2020 18:26:43 |
|                           |                       |                      |
| User entered 'Yes (Y)'    | Emily Carney (b) (4)  | 28 Sep 2020 14:11:47 |
|                           | (b) (4)               |                      |

US3802074

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:55:48

Date of assessment (*dd MMM yyyy*)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 29 Apr 2021 15:42:08 |
|                            |                       |                      |
| User signature succeeded.  | Judith Martin (b) (4) | 28 Jan 2021 18:19:31 |
| DataPoint Verified.        | (b) (4)               |                      |
|                            | (b) (4), (b) (6)      | 07 Oct 2020 18:26:45 |
| User entered '28 Sep 2020' | Emily Carney (b) (4)  | 28 Sep 2020 14:11:47 |
|                            | (b) (4)               |                      |

US3802074

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:55:48

Time of assessment (00:00-23:59)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 29 Apr 2021 15:42:08 |
|                           |                       |                      |
|                           |                       |                      |
| User signature succeeded. | Judith Martin (b) (4) | 28 Jan 2021 18:19:31 |
|                           | (b) (4)               |                      |
| DataPoint Verified.       | (b) (4), (b) (6)      | 07 Oct 2020 18:26:47 |
|                           |                       |                      |
| User entered '09:56'      | Emily Carney (b) (4)  | 28 Sep 2020 14:11:47 |
|                           | (b) (4)               |                      |

US3802074

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:55:48

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

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 29 Apr 2021 15:42:08 |
|                                  |                  |                      |
|                                  |                  |                      |
| User entered '28 Sep 2020 09:56' | System           | 28 Sep 2020 14:11:47 |

US3802074

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:55:48

Temperature (xxx.x)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 29 Apr 2021 15:42:08 |
|                           |                       |                      |
|                           |                       |                      |
| User signature succeeded. | Judith Martin (b) (4) | 28 Jan 2021 18:19:31 |
|                           | (b) (4)               |                      |
| DataPoint Verified.       | (b) (4), (b) (6)      | 07 Oct 2020 18:26:49 |
|                           |                       |                      |
| User entered '96.8' F     | Emily Carney (b) (4)  | 28 Sep 2020 14:11:47 |
|                           | (b) (4)               |                      |

US3802074

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:55:48

[Route of measurement](#)

| Audit                        | User                  | Time (GMT)           |
|------------------------------|-----------------------|----------------------|
| Data hard locked.            | (b) (4), (b) (6)      | 29 Apr 2021 15:42:08 |
|                              |                       |                      |
|                              |                       |                      |
| User signature succeeded.    | Judith Martin (b) (4) | 28 Jan 2021 18:19:31 |
|                              | (b) (4)               |                      |
| DataPoint Verified.          | (b) (4), (b) (6)      | 07 Oct 2020 18:26:52 |
|                              |                       |                      |
| User entered 'Other (Other)' | Emily Carney (b) (4)  | 28 Sep 2020 14:11:47 |
|                              | (b) (4)               |                      |

US3802074

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:55:48

[If Other, specify](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 29 Apr 2021 15:42:08 |
|                           |                       |                      |
|                           |                       |                      |
| User signature succeeded. | Judith Martin (b) (4) | 28 Jan 2021 18:19:31 |
|                           | (b) (4)               |                      |
| DataPoint Verified.       | (b) (4), (b) (6)      | 07 Oct 2020 18:26:55 |
|                           |                       |                      |
| User entered 'Infrared'   | Emily Carney (b) (4)  | 28 Sep 2020 14:11:47 |
|                           | (b) (4)               |                      |

US3802074

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:55:48

[Pulse \(xxx\)](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 29 Apr 2021 15:42:08 |
|                           |                       |                      |
|                           |                       |                      |
| User signature succeeded. | Judith Martin (b) (4) | 28 Jan 2021 18:19:31 |
|                           | (b) (4)               |                      |
| DataPoint Verified.       | (b) (4), (b) (6)      | 07 Oct 2020 18:26:58 |
|                           |                       |                      |
| User entered '66'         | Emily Carney (b) (4)  | 28 Sep 2020 14:11:47 |
|                           | (b) (4)               |                      |



**US3802074**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:55:48**

[Pulse units](#)

| Audit              | User             | Time (GMT)           |
|--------------------|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 29 Apr 2021 15:42:08 |
| User entered 'bpm' | System           | 28 Sep 2020 14:11:47 |

US3802074

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:55:48

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

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                | 29 Apr 2021 15:42:08 |
| User signature succeeded. | Judith Martin (b) (4)           | 28 Jan 2021 18:19:31 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)     | 07 Oct 2020 18:27:10 |
| User entered '18'         | Emily Carney (b) (4)<br>(b) (4) | 28 Sep 2020 14:11:47 |

US3802074

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:55:48

[Respiratory Rate units](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6) | 29 Apr 2021 15:42:08 |
| User entered 'breaths/min' | System           | 28 Sep 2020 14:11:47 |

US3802074

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:55:48

Systolic Blood Pressure (xxx)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 29 Apr 2021 15:42:08 |
|                           |                       |                      |
|                           |                       |                      |
| User signature succeeded. | Judith Martin (b) (4) | 28 Jan 2021 18:19:31 |
|                           | (b) (4)               |                      |
| DataPoint Verified.       | (b) (4), (b) (6)      | 07 Oct 2020 18:27:12 |
|                           |                       |                      |
| User entered '155'        | Emily Carney (b) (4)  | 28 Sep 2020 14:11:47 |
|                           | (b) (4)               |                      |

US3802074

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:55:48

[Systolic Blood Pressure units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 29 Apr 2021 15:42:08 |
| User entered 'mmHg' | System           | 28 Sep 2020 14:11:47 |

US3802074

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:55:48

Diastolic Blood Pressure (xxx)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 29 Apr 2021 15:42:08 |
|                           |                       |                      |
|                           |                       |                      |
| User signature succeeded. | Judith Martin (b) (4) | 28 Jan 2021 18:19:31 |
|                           | (b) (4)               |                      |
| DataPoint Verified.       | (b) (4), (b) (6)      | 07 Oct 2020 18:27:14 |
|                           |                       |                      |
| User entered '93'         | Emily Carney (b) (4)  | 28 Sep 2020 14:11:47 |
|                           | (b) (4)               |                      |

US3802074

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:55:48

Diastolic Blood Pressure units

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 29 Apr 2021 15:42:08 |
| User entered 'mmHg' | System           | 28 Sep 2020 14:11:47 |

US3802074

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:55:48

[Was the physical examination performed?](#)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                | 29 Apr 2021 15:42:08 |
| User signature succeeded. | Judith Martin (b) (4)           | 28 Jan 2021 18:19:31 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)     | 07 Oct 2020 18:27:35 |
| User entered 'No (N)'     | Emily Carney (b) (4)<br>(b) (4) | 28 Sep 2020 13:25:36 |



US3802074

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:55:48

Date of examination (dd MMM yyyy)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 29 Apr 2021 15:42:08 |
|                           |                       |                      |
|                           |                       |                      |
| User signature succeeded. | Judith Martin (b) (4) | 28 Jan 2021 18:19:31 |
|                           | (b) (4)               |                      |
| DataPoint Verified.       | (b) (4), (b) (6)      | 07 Oct 2020 18:27:35 |
|                           |                       |                      |
| User entered empty.       | Emily Carney (b) (4)  | 28 Sep 2020 13:25:36 |
|                           | (b) (4)               |                      |

US3802074

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:55:48

[Was study treatment given?](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 29 Apr 2021 15:42:08 |
|                           |                       |                      |
|                           |                       |                      |
| User signature succeeded. | Judith Martin (b) (4) | 28 Jan 2021 18:19:31 |
|                           | (b) (4)               |                      |
| DataPoint Verified.       | (b) (4), (b) (6)      | 07 Oct 2020 18:27:57 |
|                           |                       |                      |
| User entered 'Yes (Y)'    | Emily Carney (b) (4)  | 28 Sep 2020 13:28:15 |
|                           | (b) (4)               |                      |

US3802074

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:55:48

[If No, reason not given](#)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                | 29 Apr 2021 15:42:08 |
| User signature succeeded. | Judith Martin (b) (4)           | 28 Jan 2021 18:19:31 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)     | 07 Oct 2020 18:27:57 |
| User entered empty.       | Emily Carney (b) (4)<br>(b) (4) | 28 Sep 2020 13:28:15 |

US3802074

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:55:48

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

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 29 Apr 2021 15:42:08 |
|                           |                       |                      |
|                           |                       |                      |
| User signature succeeded. | Judith Martin (b) (4) | 28 Jan 2021 18:19:31 |
|                           | (b) (4)               |                      |
| DataPoint Verified.       | (b) (4), (b) (6)      | 07 Oct 2020 18:27:57 |
|                           |                       |                      |
| User entered empty.       | Emily Carney (b) (4)  | 28 Sep 2020 13:28:15 |
|                           | (b) (4)               |                      |

US3802074

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:55:48

[What was the study treatment?](#)

| Audit                               | User             | Time (GMT)           |
|-------------------------------------|------------------|----------------------|
| Data hard locked.                   | (b) (4), (b) (6) | 29 Apr 2021 15:42:08 |
|                                     |                  |                      |
|                                     |                  |                      |
| User entered 'MRNA-1273 OR PLACEBO' | System           | 28 Sep 2020 13:28:15 |

US3802074

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:55:48

What was the treatment date? (dd MMM yyyy)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 29 Apr 2021 15:42:08 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | Judith Martin (b) (4) | 28 Jan 2021 18:19:31 |
|                            | (b) (4)               |                      |
| DataPoint Verified.        | (b) (4), (b) (6)      | 07 Oct 2020 18:27:57 |
|                            |                       |                      |
| User entered '28 Sep 2020' | Emily Carney (b) (4)  | 28 Sep 2020 13:28:15 |
|                            | (b) (4)               |                      |

US3802074

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:55:48

[What was the treatment time? \(00:00-23:59\)](#)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                | 29 Apr 2021 15:42:08 |
| User signature succeeded. | Judith Martin (b) (4)           | 28 Jan 2021 18:19:31 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)     | 07 Oct 2020 18:27:57 |
| User entered '09:26'      | Emily Carney (b) (4)<br>(b) (4) | 28 Sep 2020 13:28:15 |

US3802074

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:55:48

[Treatment Date and Time \(derived\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 29 Apr 2021 15:42:08 |
| User entered '28 Sep 2020 09:26' | System           | 28 Sep 2020 13:28:15 |



US3802074

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:55:48

[Which arm was used to give treatment?](#)

| Audit                              | User                  | Time (GMT)           |
|------------------------------------|-----------------------|----------------------|
| Data hard locked.                  | (b) (4), (b) (6)      | 29 Apr 2021 15:42:08 |
|                                    |                       |                      |
|                                    |                       |                      |
| User signature succeeded.          | Judith Martin (b) (4) | 28 Jan 2021 18:19:31 |
|                                    | (b) (4)               |                      |
| DataPoint Verified.                | (b) (4), (b) (6)      | 07 Oct 2020 18:27:57 |
|                                    |                       |                      |
| User entered 'Left Arm (LEFT ARM)' | Emily Carney (b) (4)  | 28 Sep 2020 13:28:15 |
|                                    | (b) (4)               |                      |

US3802074

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:55:48

[What was the frequency of the study treatment dosing?](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 29 Apr 2021 15:42:08 |
| DataPoint Verified. |                  | 07 Oct 2020 18:27:57 |
| User entered 'ONCE' | System           | 28 Sep 2020 13:28:15 |

US3802074

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:55:48

What was the route of administration for the study treatment?

| Audit                        | User             | Time (GMT)           |
|------------------------------|------------------|----------------------|
| Data hard locked.            | (b) (4), (b) (6) | 29 Apr 2021 15:42:08 |
| User entered 'INTRAMUSCULAR' | System           | 28 Sep 2020 13:28:15 |

US3802074

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:55:48

[Was the sample collected?](#)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                | 29 Apr 2021 15:42:08 |
| User signature succeeded. | Judith Martin (b) (4)           | 28 Jan 2021 18:19:31 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)     | 07 Oct 2020 18:28:23 |
| User entered 'Yes (Y)'    | Emily Carney (b) (4)<br>(b) (4) | 28 Sep 2020 13:25:56 |

US3802074

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:55:48

Collection date (*dd MMM yyyy*)

| Audit                      | User                            | Time (GMT)           |
|----------------------------|---------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                | 29 Apr 2021 15:42:08 |
| User signature succeeded.  | Judith Martin (b) (4)           | 28 Jan 2021 18:19:31 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6)     | 07 Oct 2020 18:28:23 |
| User entered '28 Sep 2020' | Emily Carney (b) (4)<br>(b) (4) | 28 Sep 2020 13:25:56 |

US3802074

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:55:48

Collection time (00:00-23:59)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                | 29 Apr 2021 15:42:08 |
| User signature succeeded. | Judith Martin (b) (4)           | 28 Jan 2021 18:19:31 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)     | 07 Oct 2020 18:28:23 |
| User entered '09:13'      | Emily Carney (b) (4)<br>(b) (4) | 28 Sep 2020 13:25:56 |

**US3802074**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:55:48**

[Collection date and time \(derived\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 29 Apr 2021 15:42:08 |
| User entered '28 Sep 2020 09:13' | System           | 28 Sep 2020 13:25:56 |

US3802074

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:55:48

Collection date (*dd MMM yyyy*)

| Audit                      | User                            | Time (GMT)           |
|----------------------------|---------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                | 29 Apr 2021 15:42:08 |
| User signature succeeded.  | Judith Martin (b) (4)           | 28 Jan 2021 18:19:31 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6)     | 07 Oct 2020 18:28:35 |
| User entered '28 Sep 2020' | Emily Carney (b) (4)<br>(b) (4) | 28 Sep 2020 13:26:17 |



US3802074

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:55:48

[Lab Test](#)

| Audit  | User                 | Time (GMT)           |
|--|----------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)     | 29 Apr 2021 15:42:08 |
|  |                      |                      |
|  |                      |                      |
|  |                      |                      |
| User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)' | Emily Carney (b) (4) | 28 Sep 2020 13:26:17 |
|  | (b) (4)              |                      |

US3802074

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:55:48

[Was the sample collected?](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 29 Apr 2021 15:42:08 |
|                           |                       |                      |
| User signature succeeded. | Judith Martin (b) (4) | 28 Jan 2021 18:19:31 |
| DataPoint Verified.       | (b) (4)               |                      |
|                           | (b) (4), (b) (6)      | 07 Oct 2020 18:28:41 |
| User entered 'Yes (Y)'    | Emily Carney (b) (4)  | 28 Sep 2020 13:26:17 |
|                           | (b) (4)               |                      |

**US3802074**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:55:48**

[Collection time \(00:00 - 23:59\)](#)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                | 29 Apr 2021 15:42:08 |
| User signature succeeded. | Judith Martin (b) (4)           | 28 Jan 2021 18:19:31 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)     | 07 Oct 2020 18:28:42 |
| User entered '09:10'      | Emily Carney (b) (4)<br>(b) (4) | 28 Sep 2020 13:26:17 |

**US3802074**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:55:48**

[Collection date and time \(derived\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 29 Apr 2021 15:42:08 |
| User entered '28 Sep 2020 09:10' | System           | 28 Sep 2020 13:26:17 |

US3802074

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:55:48

[Lab Test](#)

| Audit  | User                 | Time (GMT)           |
|--|----------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)     | 29 Apr 2021 15:42:08 |
|  |                      |                      |
|  |                      |                      |
| User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)' | Emily Carney (b) (4) | 28 Sep 2020 13:26:17 |
|  | (b) (4)              |                      |

US3802074

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:55:48

[Was the sample collected?](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 29 Apr 2021 15:42:08 |
|                           |                       |                      |
|                           |                       |                      |
| User signature succeeded. | Judith Martin (b) (4) | 28 Jan 2021 18:19:31 |
|                           | (b) (4)               |                      |
| DataPoint Verified.       | (b) (4), (b) (6)      | 07 Oct 2020 18:32:50 |
|                           |                       |                      |
| User entered 'No (N)'     | Emily Carney (b) (4)  | 28 Sep 2020 13:26:17 |
|                           | (b) (4)               |                      |

US3802074

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:55:48

Collection time (00:00 - 23:59)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 29 Apr 2021 15:42:08 |
|                           |                       |                      |
|                           |                       |                      |
| User signature succeeded. | Judith Martin (b) (4) | 28 Jan 2021 18:19:31 |
|                           | (b) (4)               |                      |
| DataPoint Verified.       | (b) (4), (b) (6)      | 07 Oct 2020 18:32:52 |
|                           |                       |                      |
| User entered empty.       | Emily Carney (b) (4)  | 28 Sep 2020 13:26:17 |
|                           | (b) (4)               |                      |

**US3802074**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:55:48**

[Collection date and time \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 29 Apr 2021 15:42:08 |
| User entered empty. | System           | 28 Sep 2020 13:26:17 |



US3802074

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:55:48

[Is the participant continuing to the next visit?](#)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                | 29 Apr 2021 15:42:08 |
| User signature succeeded. | Judith Martin (b) (4)           | 28 Jan 2021 18:19:31 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)     | 07 Oct 2020 18:32:58 |
| User entered 'Yes (Y)'    | Emily Carney (b) (4)<br>(b) (4) | 28 Sep 2020 13:26:29 |

**US3802074**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:55:48**

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:42:08 |
| User entered '1'  | System           | 28 Sep 2020 13:26:29 |

US3802074

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:55:48

**TIMEPOINT**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| Data entry locked.   | System           | 28 Sep 2020 13:28:15 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System           | 28 Sep 2020 13:28:15 |

US3802074

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:55:48

Was **TEMPERATURE** taken?

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-09-28T09:57:52', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: 'ac589826-17ef-4246-b731-904d384b32f3' User entered 'Yes (Y)' | System           | 28 Sep 2020 13:58:08 |
|   | System           | 28 Sep 2020 13:58:08 |

US3802074

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:55:48

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-09-28T09:57:58', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: 'ac589826-17ef-4246-b731-904d384b32f3' User entered '96.8' | System           | 28 Sep 2020 13:58:08 |
|  | System           | 28 Sep 2020 13:58:08 |

US3802074

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:55:48

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-09-28T09:58:01', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: 'ac589826-17ef-4246-b731-904d384b32f3' | System           | 28 Sep 2020 13:58:08 |
| User entered 'No (N)'  | System           | 28 Sep 2020 13:58:08 |

**US3802074**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 09:55:48**

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-09-28T09:58:06', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: 'ac589826-17ef-4246-b731-904d384b32f3' | System           | 28 Sep 2020 13:58:08 |
| User entered '28 Sep 2020 09:58'   | System           | 28 Sep 2020 13:58:08 |

US3802074

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:55:48

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| User entered '28 Sep 2020 09:46' | System           | 28 Sep 2020 13:28:15 |



US3802074

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:55:48

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| User entered '28 Sep 2020 12:16' | System           | 28 Sep 2020 13:28:15 |

US3802074

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:55:48

**TIMEPOINT**

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                                 | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| Data entry locked.                                | System           | 28 Sep 2020 13:28:15 |
| User entered 'Day 1, after vaccination (at home)' | System           | 28 Sep 2020 13:28:15 |

US3802074

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:55:48

Was **TEMPERATURE** taken?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-09-28T18:09:53', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '634e4276-1008-44f6-ae3d-45aba4945a90' | System           | 28 Sep 2020 22:10:09 |
| User entered 'Yes (Y)'   | System           | 28 Sep 2020 22:10:09 |

US3802074

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:55:48

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-09-28T18:09:58', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '634e4276-1008-44f6-ae3d-45aba4945a90' User entered '97.7' | System           | 28 Sep 2020 22:10:09 |
|  | System           | 28 Sep 2020 22:10:09 |

US3802074

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:55:48

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-09-28T18:10:01', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '634e4276-1008-44f6-ae3d-45aba4945a90' | System           | 28 Sep 2020 22:10:09 |
| User entered 'No (N)'  | System           | 28 Sep 2020 22:10:09 |

**US3802074**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 09:55:48**

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-09-28T18:10:06', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '634e4276-1008-44f6-ae3d-45aba4945a90' | System           | 28 Sep 2020 22:10:09 |
| User entered '28 Sep 2020 18:10'   | System           | 28 Sep 2020 22:10:09 |

**US3802074**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 09:55:48**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| User entered '28 Sep 2020 13:11' | System           | 28 Sep 2020 13:28:15 |

US3802074

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:55:48

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| User entered '29 Sep 2020 11:59' | System           | 28 Sep 2020 13:28:15 |



US3802074

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:55:48

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| Data entry locked.   | System           | 28 Sep 2020 13:28:15 |
| User entered 'Day 2' | System           | 28 Sep 2020 13:28:15 |

US3802074

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:55:48

Was **TEMPERATURE** taken?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-09-29T17:00:53', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '4f660792-f527-4b15-ba5c-9bcd1e8dea50' | System           | 29 Sep 2020 21:01:23 |
| User entered 'Yes (Y)'   | System           | 29 Sep 2020 21:01:23 |

US3802074

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:55:48

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-09-29T17:00:57', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '4f660792-f527-4b15-ba5c-9bcd1e8dea50' User entered '97.7' | System           | 29 Sep 2020 21:01:23 |
|  | System           | 29 Sep 2020 21:01:23 |

US3802074

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:55:48

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-09-29T17:01:06', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '4f660792-f527-4b15-ba5c-9bcd1e8dea50' | System           | 29 Sep 2020 21:01:23 |
| User entered 'Yes (Y)'   | System           | 29 Sep 2020 21:01:23 |

US3802074

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:55:48

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

| Audit   | User                  | Time (GMT)           |
|---|-----------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)      | 06 Mar 2021 23:14:58 |
| User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'participant was contacted' (Site from System). | (b) (4), (b) (6)      | 08 Oct 2020 15:02:13 |
| User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.'  | Lalicia Roman (b) (4) | 05 Oct 2020 18:03:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-09-29T17:01:12', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '4f660792-f527-4b15-ba5c-9bcd1e8dea50'  | (b) (4)               |                      |
| User entered '1'  | System                | 29 Sep 2020 21:01:23 |
|   | System                | 29 Sep 2020 21:01:23 |
|   | System                | 29 Sep 2020 21:01:23 |

US3802074

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:55:48

To **PREVENT** pain or fever from occurring

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-09-29T17:01:12', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '4f660792-f527-4b15-ba5c-9bcd1e8dea50' | System           | 29 Sep 2020 21:01:23 |
| User entered '0'   | System           | 29 Sep 2020 21:01:23 |

US3802074

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:55:48

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-09-29T17:01:18', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '4f660792-f527-4b15-ba5c-9bcd1e8dea50' User entered '29 Sep 2020 17:01' | System           | 29 Sep 2020 21:01:23 |
|   | System           | 29 Sep 2020 21:01:23 |

US3802074

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:55:48

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| User entered '29 Sep 2020 12:00' | System           | 28 Sep 2020 13:28:15 |



US3802074

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:55:48

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| User entered '30 Sep 2020 11:59' | System           | 28 Sep 2020 13:28:15 |

US3802074

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:55:48

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| Data entry locked.   | System           | 28 Sep 2020 13:28:15 |
| User entered 'Day 3' | System           | 28 Sep 2020 13:28:15 |

US3802074

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:55:48

Was **TEMPERATURE** taken?

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-09-30T17:29:54', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: 'a4d64bce-e676-4080-915a-f1b541242bfc' User entered 'Yes (Y)' | System           | 30 Sep 2020 21:30:11 |
|   | System           | 30 Sep 2020 21:30:11 |

US3802074

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:55:48

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-09-30T17:29:59', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: 'a4d64bce-e676-4080-915a-f1b541242bfc' User entered '97.1' | System           | 30 Sep 2020 21:30:11 |
|  | System           | 30 Sep 2020 21:30:11 |

US3802074

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:55:48

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-09-30T17:30:02', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: 'a4d64bce-e676-4080-915a-f1b541242bfc' User entered 'No (N)' | System           | 30 Sep 2020 21:30:11 |
|  | System           | 30 Sep 2020 21:30:11 |

**US3802074**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 09:55:48**

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-09-30T17:30:08', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: 'a4d64bce-e676-4080-915a-f1b541242bfc' User entered '30 Sep 2020 17:30' | System           | 30 Sep 2020 21:30:11 |
|   | System           | 30 Sep 2020 21:30:11 |

US3802074

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:55:48

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| User entered '30 Sep 2020 12:00' | System           | 28 Sep 2020 13:28:15 |

US3802074

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:55:48

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| User entered '01 Oct 2020 11:59' | System           | 28 Sep 2020 13:28:15 |



US3802074

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:55:48

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| Data entry locked.   | System           | 28 Sep 2020 13:28:15 |
| User entered 'Day 4' | System           | 28 Sep 2020 13:28:15 |

US3802074

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:55:48

Was **TEMPERATURE** taken?

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-10-01T19:02:31', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: 'b6c760df-b93a-4712-a7c7-2e093f18efda' User entered 'Yes (Y)' | System           | 01 Oct 2020 23:02:52 |
|   | System           | 01 Oct 2020 23:02:52 |

US3802074

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:55:48

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-10-01T19:02:35', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: 'b6c760df-b93a-4712-a7c7-2e093f18efda' User entered '96.1' | System           | 01 Oct 2020 23:02:52 |
|  | System           | 01 Oct 2020 23:02:52 |

US3802074

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:55:48

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-10-01T19:02:39', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: 'b6c760df-b93a-4712-a7c7-2e093f18efda' | System           | 01 Oct 2020 23:02:52 |
| User entered 'Yes (Y)'   | System           | 01 Oct 2020 23:02:52 |

US3802074

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:55:48

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

| Audit   | User                  | Time (GMT)           |
|---|-----------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)      | 06 Mar 2021 23:14:58 |
| User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'participant was contacted' (Site from System). | (b) (4)               | 08 Oct 2020 15:02:18 |
| User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.'  | Lalicia Roman (b) (4) | 05 Oct 2020 18:04:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-10-01T19:02:45', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: 'b6c760df-b93a-4712-a7c7-2e093f18efda'  | (b) (4)               |                      |
| User entered '1'  | System                | 01 Oct 2020 23:02:52 |
|   | System                | 01 Oct 2020 23:02:52 |
|   | System                | 01 Oct 2020 23:02:52 |

US3802074

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:55:48

To **PREVENT** pain or fever from occurring

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-10-01T19:02:45', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: 'b6c760df-b93a-4712-a7c7-2e093f18efda' User entered '0' | System           | 01 Oct 2020 23:02:52 |
|   | System           | 01 Oct 2020 23:02:52 |

**US3802074**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 10 Jun 2021 09:55:48**

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-10-01T19:02:49', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: 'b6c760df-b93a-4712-a7c7-2e093f18efda' User entered '01 Oct 2020 19:02' | System           | 01 Oct 2020 23:02:52 |
|   | System           | 01 Oct 2020 23:02:52 |

US3802074

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:55:48

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| User entered '01 Oct 2020 12:00' | System           | 28 Sep 2020 13:28:15 |



US3802074

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:55:48

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| User entered '02 Oct 2020 11:59' | System           | 28 Sep 2020 13:28:15 |

US3802074

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:55:48

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| Data entry locked.   | System           | 28 Sep 2020 13:28:15 |
| User entered 'Day 5' | System           | 28 Sep 2020 13:28:15 |

US3802074

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:55:48

Was **TEMPERATURE** taken?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-10-02T17:20:22', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: 'cd5c3e3c-933f-49d4-924b-9f7e62fe53d0' | System           | 02 Oct 2020 21:20:43 |
| User entered 'Yes (Y)'   | System           | 02 Oct 2020 21:20:43 |

US3802074

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:55:48

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-10-02T17:20:28', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: 'cd5c3e3c-933f-49d4-924b-9f7e62fe53d0' User entered '97.5' | System           | 02 Oct 2020 21:20:43 |
|  | System           | 02 Oct 2020 21:20:43 |

US3802074

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:55:48

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-10-02T17:20:37', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: 'cd5c3e3c-933f-49d4-924b-9f7e62fe53d0' | System           | 02 Oct 2020 21:20:43 |
| User entered 'No (N)'  | System           | 02 Oct 2020 21:20:43 |

US3802074

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:55:48

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-10-02T17:20:41', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: 'cd5c3e3c-933f-49d4-924b-9f7e62fe53d0' User entered '02 Oct 2020 17:20' | System           | 02 Oct 2020 21:20:43 |
|   | System           | 02 Oct 2020 21:20:43 |

US3802074

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:55:48

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| User entered '02 Oct 2020 12:00' | System           | 28 Sep 2020 13:28:15 |

US3802074

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:55:48

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| User entered '03 Oct 2020 11:59' | System           | 28 Sep 2020 13:28:15 |



US3802074

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:55:48

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| Data entry locked.   | System           | 28 Sep 2020 13:28:15 |
| User entered 'Day 6' | System           | 28 Sep 2020 13:28:15 |

US3802074

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:55:48

Was **TEMPERATURE** taken?

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-10-03T17:04:54', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: 'b442dc09-3da2-48b5-b572-67a232e176f1' User entered 'Yes (Y)' | System           | 03 Oct 2020 21:05:09 |
|   | System           | 03 Oct 2020 21:05:09 |

US3802074

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:55:48

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-10-03T17:05:01', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: 'b442dc09-3da2-48b5-b572-67a232e176f1' User entered '98.0' | System           | 03 Oct 2020 21:05:09 |
|  | System           | 03 Oct 2020 21:05:09 |

US3802074

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:55:48

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-10-03T17:05:03', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: 'b442dc09-3da2-48b5-b572-67a232e176f1' User entered 'No (N)' | System           | 03 Oct 2020 21:05:09 |
|  | System           | 03 Oct 2020 21:05:09 |

US3802074

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:55:48

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-10-03T17:05:07', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: 'b442dc09-3da2-48b5-b572-67a232e176f1' User entered '03 Oct 2020 17:05' | System           | 03 Oct 2020 21:05:09 |
|   | System           | 03 Oct 2020 21:05:09 |

**US3802074**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 09:55:48**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| User entered '03 Oct 2020 12:00' | System           | 28 Sep 2020 13:28:15 |

US3802074

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:55:48

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| User entered '04 Oct 2020 11:59' | System           | 28 Sep 2020 13:28:15 |

US3802074

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:55:48

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| Data entry locked.   | System           | 28 Sep 2020 13:28:15 |
| User entered 'Day 7' | System           | 28 Sep 2020 13:28:15 |



US3802074

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:55:48

Was **TEMPERATURE** taken?

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-10-04T22:30:37', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '0235c315-2757-4fb1-b8b8-fcc5bc7b515d' User entered 'Yes (Y)' | System           | 05 Oct 2020 02:30:55 |
|   | System           | 05 Oct 2020 02:30:55 |

US3802074

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:55:48

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-10-04T22:30:46', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '0235c315-2757-4fb1-b8b8-fcc5bc7b515d' User entered '97.8' | System           | 05 Oct 2020 02:30:55 |
|  | System           | 05 Oct 2020 02:30:55 |

US3802074

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:55:48

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-10-04T22:30:48', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '0235c315-2757-4fb1-b8b8-fcc5bc7b515d' User entered 'No (N)' | System           | 05 Oct 2020 02:30:55 |
|  | System           | 05 Oct 2020 02:30:55 |

**US3802074**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 09:55:48**

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-10-04T22:30:51', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '0235c315-2757-4fb1-b8b8-fcc5bc7b515d' User entered '04 Oct 2020 22:30' | System           | 05 Oct 2020 02:30:55 |
|   | System           | 05 Oct 2020 02:30:55 |

US3802074

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:55:48

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| User entered '04 Oct 2020 12:00' | System           | 28 Sep 2020 13:28:15 |

US3802074

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:55:48

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| User entered '05 Oct 2020 11:59' | System           | 28 Sep 2020 13:28:15 |

US3802074

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:55:48

**TIMEPOINT**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| Data entry locked.   | System           | 28 Sep 2020 13:28:15 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System           | 28 Sep 2020 13:28:15 |

US3802074

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:55:48

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-09-28T09:58:22', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '91aa9706-23e6-49c9-b075-e583bb889d8e' | System           | 28 Sep 2020 13:58:48 |
| User entered 'None (1)'  | System           | 28 Sep 2020 13:58:48 |



US3802074

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:55:48

Is there any REDNESS AT INJECTION SITE?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-09-28T09:58:33', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '91aa9706-23e6-49c9-b075-e583bb889d8e' User entered 'No (N)' | System           | 28 Sep 2020 13:58:48 |
|  | System           | 28 Sep 2020 13:58:48 |

US3802074

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:55:48

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-09-28T09:58:36', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '91aa9706-23e6-49c9-b075-e583bb889d8e' User entered 'No (N)' | System           | 28 Sep 2020 13:58:48 |
|  | System           | 28 Sep 2020 13:58:48 |

US3802074

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:55:48

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-09-28T09:58:40', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '91aa9706-23e6-49c9-b075-e583bb889d8e' | System           | 28 Sep 2020 13:58:48 |
| User entered 'None (1)'  | System           | 28 Sep 2020 13:58:48 |

**US3802074**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 09:55:48**

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-09-28T09:58:44', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '91aa9706-23e6-49c9-b075-e583bb889d8e' User entered '28 Sep 2020 09:58' | System           | 28 Sep 2020 13:58:48 |
|   | System           | 28 Sep 2020 13:58:48 |

US3802074

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:55:48

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| User entered '28 Sep 2020 09:46' | System           | 28 Sep 2020 13:28:15 |

US3802074

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:55:48

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| User entered '28 Sep 2020 12:16' | System           | 28 Sep 2020 13:28:15 |

US3802074

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:55:48

**TIMEPOINT**

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                                 | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| Data entry locked.                                | System           | 28 Sep 2020 13:28:15 |
| User entered 'Day 1, after vaccination (at home)' | System           | 28 Sep 2020 13:28:15 |

US3802074

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:55:48

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-09-28T18:10:17', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '52955ddb-a649-4e22-9aa0-427fdb5027ba' | System           | 28 Sep 2020 22:10:52 |
| User entered 'Does not interfere with activity (2)'  | System           | 28 Sep 2020 22:10:52 |



US3802074

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:55:48

Is there any REDNESS AT INJECTION SITE?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-09-28T18:10:31', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '52955ddb-a649-4e22-9aa0-427fdb5027ba' User entered 'No (N)' | System           | 28 Sep 2020 22:10:52 |
|  | System           | 28 Sep 2020 22:10:52 |

US3802074

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:55:48

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-09-28T18:10:36', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '52955ddb-a649-4e22-9aa0-427fdb5027ba' User entered 'No (N)' | System           | 28 Sep 2020 22:10:52 |
|  | System           | 28 Sep 2020 22:10:52 |

US3802074

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:55:48

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-09-28T18:10:47', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '52955ddb-a649-4e22-9aa0-427fdb5027ba' | System           | 28 Sep 2020 22:10:52 |
| User entered 'None (1)'  | System           | 28 Sep 2020 22:10:52 |

US3802074

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:55:48

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-09-28T18:10:51', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '52955ddb-a649-4e22-9aa0-427fdb5027ba' User entered '28 Sep 2020 18:10' | System           | 28 Sep 2020 22:10:52 |
|   | System           | 28 Sep 2020 22:10:52 |

**US3802074**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 09:55:48**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| User entered '28 Sep 2020 13:11' | System           | 28 Sep 2020 13:28:15 |

US3802074

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:55:48

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| User entered '29 Sep 2020 11:59' | System           | 28 Sep 2020 13:28:15 |

US3802074

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:55:48

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| Data entry locked.   | System           | 28 Sep 2020 13:28:15 |
| User entered 'Day 2' | System           | 28 Sep 2020 13:28:15 |

US3802074

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:55:48

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-09-29T17:01:54', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: 'c06db3c2-b1c1-4c86-baa0-0b84ed6515a3' | System           | 29 Sep 2020 21:02:13 |
| User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity (3)'   | System           | 29 Sep 2020 21:02:13 |



US3802074

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:55:48

Is there any REDNESS AT INJECTION SITE?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-09-29T17:01:58', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: 'c06db3c2-b1c1-4c86-baa0-0b84ed6515a3' User entered 'No (N)' | System           | 29 Sep 2020 21:02:13 |
|  | System           | 29 Sep 2020 21:02:13 |

US3802074

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:55:48

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-09-29T17:02:00', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: 'c06db3c2-b1c1-4c86-baa0-0b84ed6515a3' | System           | 29 Sep 2020 21:02:13 |
| User entered 'No (N)'  | System           | 29 Sep 2020 21:02:13 |

US3802074

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:55:48

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-09-29T17:02:06', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: 'c06db3c2-b1c1-4c86-baa0-0b84ed6515a3' | System           | 29 Sep 2020 21:02:13 |
| User entered 'None (1)'  | System           | 29 Sep 2020 21:02:13 |

**US3802074**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 09:55:48**

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-09-29T17:02:11', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: 'c06db3c2-b1c1-4c86-baa0-0b84ed6515a3' User entered '29 Sep 2020 17:02' | System           | 29 Sep 2020 21:02:13 |
|   | System           | 29 Sep 2020 21:02:13 |

US3802074

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:55:48

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| User entered '29 Sep 2020 12:00' | System           | 28 Sep 2020 13:28:15 |

US3802074

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:55:48

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| User entered '30 Sep 2020 11:59' | System           | 28 Sep 2020 13:28:15 |

US3802074

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:55:48

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| Data entry locked.   | System           | 28 Sep 2020 13:28:15 |
| User entered 'Day 3' | System           | 28 Sep 2020 13:28:15 |

US3802074

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:55:48

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-09-30T17:30:13', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: 'af9e2ebc-053d-4dbc-a654-e1daae9bb3a7' | System           | 30 Sep 2020 21:30:50 |
| User entered 'Does not interfere with activity (2)'  | System           | 30 Sep 2020 21:30:50 |



US3802074

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:55:48

Is there any REDNESS AT INJECTION SITE?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-09-30T17:30:17', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: 'af9e2ebc-053d-4dbc-a654-e1daae9bb3a7' User entered 'No (N)' | System           | 30 Sep 2020 21:30:50 |
|  | System           | 30 Sep 2020 21:30:50 |

US3802074

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:55:48

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-09-30T17:30:34', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: 'af9e2ebc-053d-4dbc-a654-e1daae9bb3a7' | System           | 30 Sep 2020 21:30:50 |
| User entered 'No (N)'  | System           | 30 Sep 2020 21:30:50 |

US3802074

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:55:48

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-09-30T17:30:42', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: 'af9e2ebc-053d-4dbc-a654-e1daae9bb3a7' | System           | 30 Sep 2020 21:30:50 |
| User entered 'None (1)'  | System           | 30 Sep 2020 21:30:50 |

**US3802074**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 09:55:48**

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-09-30T17:30:48', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: 'af9e2ebc-053d-4dbc-a654-e1daae9bb3a7' User entered '30 Sep 2020 17:30' | System           | 30 Sep 2020 21:30:50 |
|   | System           | 30 Sep 2020 21:30:50 |

**US3802074**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 09:55:48**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| User entered '30 Sep 2020 12:00' | System           | 28 Sep 2020 13:28:15 |

US3802074

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:55:48

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| User entered '01 Oct 2020 11:59' | System           | 28 Sep 2020 13:28:15 |

US3802074

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:55:48

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| Data entry locked.   | System           | 28 Sep 2020 13:28:15 |
| User entered 'Day 4' | System           | 28 Sep 2020 13:28:15 |

US3802074

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:55:48

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-10-01T19:02:57', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: 'ab53a5cb-6ece-4481-a40a-d2553b2cb666' | System           | 01 Oct 2020 23:03:17 |
| User entered 'Does not interfere with activity (2)'  | System           | 01 Oct 2020 23:03:17 |



US3802074

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:55:48

Is there any REDNESS AT INJECTION SITE?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-10-01T19:02:59', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: 'ab53a5cb-6ece-4481-a40a-d2553b2cb666' | System           | 01 Oct 2020 23:03:17 |
| User entered 'No (N)'  | System           | 01 Oct 2020 23:03:17 |

US3802074

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:55:48

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-10-01T19:03:02', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: 'ab53a5cb-6ece-4481-a40a-d2553b2cb666' | System           | 01 Oct 2020 23:03:17 |
| User entered 'No (N)'  | System           | 01 Oct 2020 23:03:17 |

US3802074

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:55:48

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-10-01T19:03:06', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: 'ab53a5cb-6ece-4481-a40a-d2553b2cb666' | System           | 01 Oct 2020 23:03:17 |
| User entered 'None (1)'  | System           | 01 Oct 2020 23:03:17 |

**US3802074**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 09:55:48**

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-10-01T19:03:14', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: 'ab53a5cb-6ece-4481-a40a-d2553b2cb666' User entered '01 Oct 2020 19:03' | System           | 01 Oct 2020 23:03:17 |
|   | System           | 01 Oct 2020 23:03:17 |

US3802074

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:55:48

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| User entered '01 Oct 2020 12:00' | System           | 28 Sep 2020 13:28:15 |

US3802074

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:55:48

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| User entered '02 Oct 2020 11:59' | System           | 28 Sep 2020 13:28:15 |

US3802074

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:55:48

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| Data entry locked.   | System           | 28 Sep 2020 13:28:15 |
| User entered 'Day 5' | System           | 28 Sep 2020 13:28:15 |

US3802074

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:55:48

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-10-02T17:20:46', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '6c03268d-ed65-4857-9ff1-d0e94a8f1ca6' | System           | 02 Oct 2020 21:21:00 |
| User entered 'Does not interfere with activity (2)'  | System           | 02 Oct 2020 21:21:00 |



US3802074

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:55:48

Is there any REDNESS AT INJECTION SITE?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-10-02T17:20:49', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '6c03268d-ed65-4857-9ff1-d0e94a8f1ca6' | System           | 02 Oct 2020 21:21:00 |
| User entered 'No (N)'  | System           | 02 Oct 2020 21:21:00 |

US3802074

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:55:48

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-10-02T17:20:52', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '6c03268d-ed65-4857-9ff1-d0e94a8f1ca6' | System           | 02 Oct 2020 21:21:00 |
| User entered 'No (N)'  | System           | 02 Oct 2020 21:21:00 |

US3802074

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:55:48

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-10-02T17:20:55', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '6c03268d-ed65-4857-9ff1-d0e94a8f1ca6' | System           | 02 Oct 2020 21:21:00 |
| User entered 'None (1)'  | System           | 02 Oct 2020 21:21:00 |

**US3802074**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:55:48**

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-10-02T17:20:58', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '6c03268d-ed65-4857-9ff1-d0e94a8f1ca6' User entered '02 Oct 2020 17:20' | System           | 02 Oct 2020 21:21:00 |
|   | System           | 02 Oct 2020 21:21:00 |

**US3802074**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:55:48**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| User entered '02 Oct 2020 12:00' | System           | 28 Sep 2020 13:28:15 |

US3802074

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:55:48

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| User entered '03 Oct 2020 11:59' | System           | 28 Sep 2020 13:28:15 |

US3802074

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:55:48

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| Data entry locked.   | System           | 28 Sep 2020 13:28:15 |
| User entered 'Day 6' | System           | 28 Sep 2020 13:28:15 |

US3802074

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:55:48

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-10-03T17:05:10', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '26de3b27-e83a-4a66-bf58-1c3823b56eea' User entered 'None (1)' | System           | 03 Oct 2020 21:05:24 |
|  | System           | 03 Oct 2020 21:05:24 |



US3802074

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:55:48

Is there any REDNESS AT INJECTION SITE?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-10-03T17:05:13', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '26de3b27-e83a-4a66-bf58-1c3823b56eea' User entered 'No (N)' | System           | 03 Oct 2020 21:05:24 |
|  | System           | 03 Oct 2020 21:05:24 |

US3802074

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:55:48

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-10-03T17:05:15', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '26de3b27-e83a-4a66-bf58-1c3823b56eea' User entered 'No (N)' | System           | 03 Oct 2020 21:05:24 |
|  | System           | 03 Oct 2020 21:05:24 |

US3802074

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:55:48

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-10-03T17:05:18', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '26de3b27-e83a-4a66-bf58-1c3823b56eea' User entered 'None (1)' | System           | 03 Oct 2020 21:05:24 |
|  | System           | 03 Oct 2020 21:05:24 |

**US3802074**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:55:48**

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-10-03T17:05:21', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '26de3b27-e83a-4a66-bf58-1c3823b56eea' User entered '03 Oct 2020 17:05' | System           | 03 Oct 2020 21:05:24 |
|   | System           | 03 Oct 2020 21:05:24 |

**US3802074**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:55:48**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| User entered '03 Oct 2020 12:00' | System           | 28 Sep 2020 13:28:15 |

US3802074

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:55:48

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| User entered '04 Oct 2020 11:59' | System           | 28 Sep 2020 13:28:15 |

US3802074

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:55:48

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| Data entry locked.   | System           | 28 Sep 2020 13:28:15 |
| User entered 'Day 7' | System           | 28 Sep 2020 13:28:15 |

US3802074

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:55:48

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-10-04T22:30:55', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '97c01598-3ea1-40a9-9ce0-778defe4de10' | System           | 05 Oct 2020 02:31:10 |
| User entered 'None (1)'  | System           | 05 Oct 2020 02:31:10 |



US3802074

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:55:48

Is there any REDNESS AT INJECTION SITE?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-10-04T22:30:57', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '97c01598-3ea1-40a9-9ce0-778defe4de10' | System           | 05 Oct 2020 02:31:10 |
| User entered 'No (N)'  | System           | 05 Oct 2020 02:31:10 |

US3802074

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:55:48

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-10-04T22:31:00', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '97c01598-3ea1-40a9-9ce0-778defe4de10' | System           | 05 Oct 2020 02:31:10 |
| User entered 'No (N)'  | System           | 05 Oct 2020 02:31:10 |

US3802074

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:55:48

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-10-04T22:31:02', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '97c01598-3ea1-40a9-9ce0-778defe4de10' | System           | 05 Oct 2020 02:31:10 |
| User entered 'None (1)'  | System           | 05 Oct 2020 02:31:10 |

**US3802074**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 09:55:48**

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-10-04T22:31:08', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '97c01598-3ea1-40a9-9ce0-778defe4de10' User entered '04 Oct 2020 22:31' | System           | 05 Oct 2020 02:31:10 |
|   | System           | 05 Oct 2020 02:31:10 |

US3802074

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:55:48

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| User entered '04 Oct 2020 12:00' | System           | 28 Sep 2020 13:28:15 |

US3802074

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:55:48

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| User entered '05 Oct 2020 11:59' | System           | 28 Sep 2020 13:28:15 |

US3802074

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:55:48

**TIMEPOINT**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| Data entry locked.   | System           | 28 Sep 2020 13:28:15 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System           | 28 Sep 2020 13:28:15 |

US3802074

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:55:48

**HEADACHE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-09-28T09:58:49', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: 'e51e2770-0f83-4c2f-a5f5-a537e1d4197d' User entered 'None (0)' | System           | 28 Sep 2020 13:59:14 |
|  | System           | 28 Sep 2020 13:59:14 |



US3802074

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:55:48

**FATIGUE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-09-28T09:58:52', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: 'e51e2770-0f83-4c2f-a5f5-a537e1d4197d' User entered 'None (0)' | System           | 28 Sep 2020 13:59:14 |
|  | System           | 28 Sep 2020 13:59:14 |

US3802074

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:55:48

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-09-28T09:58:54', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: 'e51e2770-0f83-4c2f-a5f5-a537e1d4197d' User entered 'None (0)' | System           | 28 Sep 2020 13:59:14 |
|  | System           | 28 Sep 2020 13:59:14 |

US3802074

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:55:48

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-09-28T09:58:57', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: 'e51e2770-0f83-4c2f-a5f5-a537e1d4197d' User entered 'None (0)' | System           | 28 Sep 2020 13:59:14 |
|  | System           | 28 Sep 2020 13:59:14 |

US3802074

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:55:48

**NAUSEA/VOMITING**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-09-28T09:59:01', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: 'e51e2770-0f83-4c2f-a5f5-a537e1d4197d' User entered 'None (0)' | System           | 28 Sep 2020 13:59:14 |
|  | System           | 28 Sep 2020 13:59:14 |

US3802074

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:55:48

**CHILLS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-09-28T09:59:03', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: 'e51e2770-0f83-4c2f-a5f5-a537e1d4197d' User entered 'None (0)' | System           | 28 Sep 2020 13:59:14 |
|  | System           | 28 Sep 2020 13:59:14 |

US3802074

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:55:48

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-09-28T09:59:07', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: 'e51e2770-0f83-4c2f-a5f5-a537e1d4197d' User entered 'No (N)' | System           | 28 Sep 2020 13:59:14 |
|  | System           | 28 Sep 2020 13:59:14 |

**US3802074**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:55:48**

[PC Time stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-09-28T09:59:11', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: 'e51e2770-0f83-4c2f-a5f5-a537e1d4197d' User entered '28 Sep 2020 09:59' | System           | 28 Sep 2020 13:59:14 |
|   | System           | 28 Sep 2020 13:59:14 |

**US3802074**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:55:48**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| User entered '28 Sep 2020 09:46' | System           | 28 Sep 2020 13:28:15 |



**US3802074**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:55:48**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| User entered '28 Sep 2020 12:16' | System           | 28 Sep 2020 13:28:15 |

US3802074

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:55:48

**TIMEPOINT**

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                                 | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| Data entry locked.                                | System           | 28 Sep 2020 13:28:15 |
| User entered 'Day 1, after vaccination (at home)' | System           | 28 Sep 2020 13:28:15 |

US3802074

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:55:48

**HEADACHE**

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-09-28T18:11:04', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '63bb9b5c-c30a-4dac-b156-8841d1b328eb' User entered 'Any use of prescription pain reliever or System prevents daily activity (3)' | System           | 28 Sep 2020 22:11:51 |

US3802074

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:55:48

**FATIGUE**

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-09-28T18:11:08', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '63bb9b5c-c30a-4dac-b156-8841d1b328eb' User entered 'No interference with activity (1)' | System           | 28 Sep 2020 22:11:51 |
|   | System           | 28 Sep 2020 22:11:51 |

US3802074

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:55:48

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-09-28T18:11:13', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '63bb9b5c-c30a-4dac-b156-8841d1b328eb' User entered 'None (0)' | System           | 28 Sep 2020 22:11:51 |
|  | System           | 28 Sep 2020 22:11:51 |

US3802074

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:55:48

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-09-28T18:11:16', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '63bb9b5c-c30a-4dac-b156-8841d1b328eb' User entered 'None (0)' | System           | 28 Sep 2020 22:11:51 |
|  | System           | 28 Sep 2020 22:11:51 |

US3802074

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:55:48

**NAUSEA/VOMITING**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-09-28T18:11:26', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '63bb9b5c-c30a-4dac-b156-8841d1b328eb' User entered 'None (0)' | System           | 28 Sep 2020 22:11:51 |
|  | System           | 28 Sep 2020 22:11:51 |

US3802074

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:55:48

**CHILLS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-09-28T18:11:31', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '63bb9b5c-c30a-4dac-b156-8841d1b328eb' User entered 'None (0)' | System           | 28 Sep 2020 22:11:51 |
|  | System           | 28 Sep 2020 22:11:51 |



US3802074

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:55:48

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-09-28T18:11:35', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '63bb9b5c-c30a-4dac-b156-8841d1b328eb' User entered 'No (N)' | System           | 28 Sep 2020 22:11:51 |
|  | System           | 28 Sep 2020 22:11:51 |

**US3802074**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:55:48**

[PC Time stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-09-28T18:11:38', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '63bb9b5c-c30a-4dac-b156-8841d1b328eb' User entered '28 Sep 2020 18:11' | System           | 28 Sep 2020 22:11:51 |
|   | System           | 28 Sep 2020 22:11:51 |

**US3802074**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:55:48**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| User entered '28 Sep 2020 13:11' | System           | 28 Sep 2020 13:28:15 |

**US3802074**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:55:48**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| User entered '29 Sep 2020 11:59' | System           | 28 Sep 2020 13:28:15 |

**US3802074**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:55:48**

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| Data entry locked.   | System           | 28 Sep 2020 13:28:15 |
| User entered 'Day 2' | System           | 28 Sep 2020 13:28:15 |

US3802074

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:55:48

**HEADACHE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-09-29T17:02:16', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '9080b1d2-18c4-4cf1-ae95-afb752ae7ede' User entered 'None (0)' | System           | 29 Sep 2020 21:02:45 |
|  | System           | 29 Sep 2020 21:02:45 |

US3802074

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:55:48

**FATIGUE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-09-29T17:02:19', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '9080b1d2-18c4-4cf1-ae95-afb752ae7ede' | System           | 29 Sep 2020 21:02:45 |
| User entered 'Some interference with activity (2)'   | System           | 29 Sep 2020 21:02:45 |

US3802074

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:55:48

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-09-29T17:02:26', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '9080b1d2-18c4-4cf1-ae95-afb752ae7ede' | System           | 29 Sep 2020 21:02:45 |
| User entered 'No interference with activity (1)'   | System           | 29 Sep 2020 21:02:45 |



US3802074

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:55:48

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-09-29T17:02:32', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '9080b1d2-18c4-4cf1-ae95-afb752ae7ede' User entered 'None (0)' | System           | 29 Sep 2020 21:02:45 |
|  | System           | 29 Sep 2020 21:02:45 |

US3802074

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:55:48

**NAUSEA/VOMITING**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-09-29T17:02:34', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '9080b1d2-18c4-4cf1-ae95-afb752ae7ede' User entered 'None (0)' | System           | 29 Sep 2020 21:02:45 |
|  | System           | 29 Sep 2020 21:02:45 |

US3802074

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:55:48

**CHILLS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-09-29T17:02:36', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '9080b1d2-18c4-4cf1-ae95-afb752ae7ede' User entered 'None (0)' | System           | 29 Sep 2020 21:02:45 |
|  | System           | 29 Sep 2020 21:02:45 |

US3802074

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:55:48

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-09-29T17:02:39', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '9080b1d2-18c4-4cf1-ae95-afb752ae7ede' User entered 'No (N)' | System           | 29 Sep 2020 21:02:45 |
|  | System           | 29 Sep 2020 21:02:45 |

**US3802074**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:55:48**

[PC Time stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-09-29T17:02:42', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '9080b1d2-18c4-4cf1-ae95-afb752ae7ede' User entered '29 Sep 2020 17:02' | System           | 29 Sep 2020 21:02:45 |
|   | System           | 29 Sep 2020 21:02:45 |

US3802074

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:55:48

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| User entered '29 Sep 2020 12:00' | System           | 28 Sep 2020 13:28:15 |

**US3802074**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:55:48**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| User entered '30 Sep 2020 11:59' | System           | 28 Sep 2020 13:28:15 |

US3802074

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:55:48

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| Data entry locked.   | System           | 28 Sep 2020 13:28:15 |
| User entered 'Day 3' | System           | 28 Sep 2020 13:28:15 |



US3802074

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:55:48

**HEADACHE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-09-30T17:30:55', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: 'd464e3ac-924b-4512-b67e-1de669898fe7' User entered 'None (0)' | System           | 30 Sep 2020 21:31:26 |
|  | System           | 30 Sep 2020 21:31:26 |

US3802074

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:55:48

**FATIGUE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-09-30T17:30:58', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: 'd464e3ac-924b-4512-b67e-1de669898fe7' | System           | 30 Sep 2020 21:31:26 |
| User entered 'No interference with activity (1)'   | System           | 30 Sep 2020 21:31:26 |

US3802074

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:55:48

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-09-30T17:31:00', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: 'd464e3ac-924b-4512-b67e-1de669898fe7' User entered 'None (0)' | System           | 30 Sep 2020 21:31:26 |
|  | System           | 30 Sep 2020 21:31:26 |

US3802074

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:55:48

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-09-30T17:31:03', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: 'd464e3ac-924b-4512-b67e-1de669898fe7' User entered 'None (0)' | System           | 30 Sep 2020 21:31:26 |
|  | System           | 30 Sep 2020 21:31:26 |

**US3802074**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:55:48**

**NAUSEA/VOMITING**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-09-30T17:31:05', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: 'd464e3ac-924b-4512-b67e-1de669898fe7' User entered 'None (0)' | System           | 30 Sep 2020 21:31:26 |
|  | System           | 30 Sep 2020 21:31:26 |

US3802074

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:55:48

**CHILLS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-09-30T17:31:07', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: 'd464e3ac-924b-4512-b67e-1de669898fe7' User entered 'None (0)' | System           | 30 Sep 2020 21:31:26 |
|  | System           | 30 Sep 2020 21:31:26 |

US3802074

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:55:48

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-09-30T17:31:15', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: 'd464e3ac-924b-4512-b67e-1de669898fe7' User entered 'No (N)' | System           | 30 Sep 2020 21:31:26 |
|  | System           | 30 Sep 2020 21:31:26 |

**US3802074**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:55:48**

[PC Time stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-09-30T17:31:20', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: 'd464e3ac-924b-4512-b67e-1de669898fe7' User entered '30 Sep 2020 17:31' | System           | 30 Sep 2020 21:31:26 |
|   | System           | 30 Sep 2020 21:31:26 |



**US3802074**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:55:48**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| User entered '30 Sep 2020 12:00' | System           | 28 Sep 2020 13:28:15 |

US3802074

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:55:48

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| User entered '01 Oct 2020 11:59' | System           | 28 Sep 2020 13:28:15 |

US3802074

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:55:48

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| Data entry locked.   | System           | 28 Sep 2020 13:28:15 |
| User entered 'Day 4' | System           | 28 Sep 2020 13:28:15 |

US3802074

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:55:48

**HEADACHE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-10-01T19:03:19', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '95a82f06-1d3c-4bfc-81ad-1ee1aeb0f43e' User entered 'None (0)' | System           | 01 Oct 2020 23:03:40 |
|  | System           | 01 Oct 2020 23:03:40 |

US3802074

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:55:48

**FATIGUE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-10-01T19:03:22', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '95a82f06-1d3c-4bfc-81ad-1ee1aeb0f43e' | System           | 01 Oct 2020 23:03:40 |
| User entered 'No interference with activity (1)'   | System           | 01 Oct 2020 23:03:40 |

US3802074

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:55:48

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-10-01T19:03:24', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '95a82f06-1d3c-4bfc-81ad-1ee1aeb0f43e' | System           | 01 Oct 2020 23:03:40 |
| User entered 'No interference with activity (1)'   | System           | 01 Oct 2020 23:03:40 |

US3802074

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:55:48

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-10-01T19:03:27', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '95a82f06-1d3c-4bfc-81ad-1ee1aeb0f43e' User entered 'None (0)' | System           | 01 Oct 2020 23:03:40 |
|  | System           | 01 Oct 2020 23:03:40 |

US3802074

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:55:48

**NAUSEA/VOMITING**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-10-01T19:03:28', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '95a82f06-1d3c-4bfc-81ad-1ee1aeb0f43e' User entered 'None (0)' | System           | 01 Oct 2020 23:03:40 |
|  | System           | 01 Oct 2020 23:03:40 |



US3802074

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:55:48

**CHILLS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-10-01T19:03:31', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '95a82f06-1d3c-4bfc-81ad-1ee1aeb0f43e' User entered 'None (0)' | System           | 01 Oct 2020 23:03:40 |
|  | System           | 01 Oct 2020 23:03:40 |

US3802074

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:55:48

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-10-01T19:03:35', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '95a82f06-1d3c-4bfc-81ad-1ee1aeb0f43e' User entered 'No (N)' | System           | 01 Oct 2020 23:03:40 |
|  | System           | 01 Oct 2020 23:03:40 |

**US3802074**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:55:48**

[PC Time stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-10-01T19:03:38', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '95a82f06-1d3c-4bfc-81ad-1ee1aeb0f43e' User entered '01 Oct 2020 19:03' | System           | 01 Oct 2020 23:03:40 |
|   | System           | 01 Oct 2020 23:03:40 |

**US3802074**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:55:48**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| User entered '01 Oct 2020 12:00' | System           | 28 Sep 2020 13:28:15 |

**US3802074**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:55:48**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| User entered '02 Oct 2020 11:59' | System           | 28 Sep 2020 13:28:15 |

US3802074

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:55:48

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| Data entry locked.   | System           | 28 Sep 2020 13:28:15 |
| User entered 'Day 5' | System           | 28 Sep 2020 13:28:15 |

US3802074

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:55:48

**HEADACHE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-10-02T17:21:02', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '716cca9f-a947-4ec9-a02f-ce9599a55c8f' User entered 'None (0)' | System           | 02 Oct 2020 21:21:30 |
|  | System           | 02 Oct 2020 21:21:30 |

US3802074

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:55:48

**FATIGUE**

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-10-02T17:21:10', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '716cca9f-a947-4ec9-a02f-ce9599a55c8f' User entered 'No interference with activity (1)' | System           | 02 Oct 2020 21:21:30 |
|   | System           | 02 Oct 2020 21:21:30 |



US3802074

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:55:48

**MUSCLE ACHES ALL OVER BODY**

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-10-02T17:21:14', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '716cca9f-a947-4ec9-a02f-ce9599a55c8f' User entered 'No interference with activity (1)' | System           | 02 Oct 2020 21:21:30 |
|   | System           | 02 Oct 2020 21:21:30 |

US3802074

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:55:48

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-10-02T17:21:16', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '716cca9f-a947-4ec9-a02f-ce9599a55c8f' User entered 'None (0)' | System           | 02 Oct 2020 21:21:30 |
|  | System           | 02 Oct 2020 21:21:30 |

US3802074

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:55:48

**NAUSEA/VOMITING**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-10-02T17:21:19', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '716cca9f-a947-4ec9-a02f-ce9599a55c8f' User entered 'None (0)' | System           | 02 Oct 2020 21:21:30 |
|  | System           | 02 Oct 2020 21:21:30 |

US3802074

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:55:48

**CHILLS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-10-02T17:21:21', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '716cca9f-a947-4ec9-a02f-ce9599a55c8f' User entered 'None (0)' | System           | 02 Oct 2020 21:21:30 |
|  | System           | 02 Oct 2020 21:21:30 |

US3802074

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:55:48

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-10-02T17:21:24', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '716cca9f-a947-4ec9-a02f-ce9599a55c8f' User entered 'No (N)' | System           | 02 Oct 2020 21:21:30 |
|  | System           | 02 Oct 2020 21:21:30 |

**US3802074**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:55:48**

[PC Time stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-10-02T17:21:28', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '716cca9f-a947-4ec9-a02f-ce9599a55c8f' User entered '02 Oct 2020 17:21' | System           | 02 Oct 2020 21:21:30 |
|   | System           | 02 Oct 2020 21:21:30 |

**US3802074**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:55:48**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| User entered '02 Oct 2020 12:00' | System           | 28 Sep 2020 13:28:15 |

US3802074

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:55:48

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| User entered '03 Oct 2020 11:59' | System           | 28 Sep 2020 13:28:15 |



US3802074

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:55:48

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| Data entry locked.   | System           | 28 Sep 2020 13:28:15 |
| User entered 'Day 6' | System           | 28 Sep 2020 13:28:15 |

US3802074

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:55:48

**HEADACHE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-10-03T17:05:25', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '3f9c4067-6625-4d3c-b251-751a1f541583' User entered 'None (0)' | System           | 03 Oct 2020 21:05:47 |
|  | System           | 03 Oct 2020 21:05:47 |

US3802074

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:55:48

**FATIGUE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-10-03T17:05:30', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '3f9c4067-6625-4d3c-b251-751a1f541583' | System           | 03 Oct 2020 21:05:47 |
| User entered 'Some interference with activity (2)'   | System           | 03 Oct 2020 21:05:47 |

US3802074

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:55:48

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-10-03T17:05:33', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '3f9c4067-6625-4d3c-b251-751a1f541583' | System           | 03 Oct 2020 21:05:47 |
| User entered 'No interference with activity (1)'   | System           | 03 Oct 2020 21:05:47 |

US3802074

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:55:48

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-10-03T17:05:35', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '3f9c4067-6625-4d3c-b251-751a1f541583' User entered 'None (0)' | System           | 03 Oct 2020 21:05:47 |
|  | System           | 03 Oct 2020 21:05:47 |

US3802074

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:55:48

**NAUSEA/VOMITING**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-10-03T17:05:37', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '3f9c4067-6625-4d3c-b251-751a1f541583' User entered 'None (0)' | System           | 03 Oct 2020 21:05:47 |
|  | System           | 03 Oct 2020 21:05:47 |

**US3802074**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:55:48**

**CHILLS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-10-03T17:05:39', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '3f9c4067-6625-4d3c-b251-751a1f541583' User entered 'None (0)' | System           | 03 Oct 2020 21:05:47 |
|  | System           | 03 Oct 2020 21:05:47 |

US3802074

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:55:48

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-10-03T17:05:42', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '3f9c4067-6625-4d3c-b251-751a1f541583' User entered 'No (N)' | System           | 03 Oct 2020 21:05:47 |
|  | System           | 03 Oct 2020 21:05:47 |



**US3802074**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:55:48**

[PC Time stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-10-03T17:05:45', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '3f9c4067-6625-4d3c-b251-751a1f541583' User entered '03 Oct 2020 17:05' | System           | 03 Oct 2020 21:05:47 |
|   | System           | 03 Oct 2020 21:05:47 |

**US3802074**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:55:48**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| User entered '03 Oct 2020 12:00' | System           | 28 Sep 2020 13:28:15 |

US3802074

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:55:48

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| User entered '04 Oct 2020 11:59' | System           | 28 Sep 2020 13:28:15 |

US3802074

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:55:48

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| Data entry locked.   | System           | 28 Sep 2020 13:28:15 |
| User entered 'Day 7' | System           | 28 Sep 2020 13:28:15 |

US3802074

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:55:48

**HEADACHE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-10-04T22:31:11', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '862691fd-8c0e-489e-a1cd-78b7d1fe2313' User entered 'None (0)' | System           | 05 Oct 2020 02:31:31 |
|  | System           | 05 Oct 2020 02:31:31 |

US3802074

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:55:48

**FATIGUE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-10-04T22:31:14', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '862691fd-8c0e-489e-a1cd-78b7d1fe2313' User entered 'None (0)' | System           | 05 Oct 2020 02:31:31 |
|  | System           | 05 Oct 2020 02:31:31 |

US3802074

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:55:48

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-10-04T22:31:15', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '862691fd-8c0e-489e-a1cd-78b7d1fe2313' User entered 'None (0)' | System           | 05 Oct 2020 02:31:31 |
|  | System           | 05 Oct 2020 02:31:31 |

**US3802074**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:55:48**

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-10-04T22:31:17', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '862691fd-8c0e-489e-a1cd-78b7d1fe2313' User entered 'None (0)' | System           | 05 Oct 2020 02:31:31 |
|  | System           | 05 Oct 2020 02:31:31 |



**US3802074**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:55:48**

**NAUSEA/VOMITING**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-10-04T22:31:18', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '862691fd-8c0e-489e-a1cd-78b7d1fe2313' User entered 'None (0)' | System           | 05 Oct 2020 02:31:31 |
|  | System           | 05 Oct 2020 02:31:31 |

US3802074

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:55:48

**CHILLS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-10-04T22:31:20', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '862691fd-8c0e-489e-a1cd-78b7d1fe2313' User entered 'None (0)' | System           | 05 Oct 2020 02:31:31 |
|  | System           | 05 Oct 2020 02:31:31 |

US3802074

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:55:48

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-10-04T22:31:24', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '862691fd-8c0e-489e-a1cd-78b7d1fe2313' | System           | 05 Oct 2020 02:31:31 |
| User entered 'No (N)'  | System           | 05 Oct 2020 02:31:31 |

**US3802074**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:55:48**

[PC Time stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-10-04T22:31:26', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '862691fd-8c0e-489e-a1cd-78b7d1fe2313' User entered '04 Oct 2020 22:31' | System           | 05 Oct 2020 02:31:31 |
|   | System           | 05 Oct 2020 02:31:31 |

US3802074

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:55:48

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| User entered '04 Oct 2020 12:00' | System           | 28 Sep 2020 13:28:15 |

US3802074

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:55:48

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| User entered '05 Oct 2020 11:59' | System           | 28 Sep 2020 13:28:15 |

**US3802074**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:55:48**

[Was Contact Attempted?](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 29 Apr 2021 15:42:08 |
|                           |                       |                      |
| User signature succeeded. | Judith Martin (b) (4) | 28 Jan 2021 18:19:31 |
| DataPoint Verified.       | (b) (4)               |                      |
|                           | (b) (4), (b) (6)      | 17 Nov 2020 14:55:10 |
|                           |                       |                      |
| User entered 'Yes (Y)'    | Lalicia Roman (b) (4) | 05 Oct 2020 18:05:24 |
|                           | (b) (4)               |                      |

US3802074

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:55:48

Date of Contact or Contact Attempt (dd MMM yyyy)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 29 Apr 2021 15:42:08 |
|                           |                       |                      |
| User signature succeeded. | Judith Martin (b) (4) | 28 Jan 2021 18:19:31 |
| DataPoint Verified.       | (b) (4)               |                      |
|                           | (b) (4), (b) (6)      | 17 Nov 2020 14:55:10 |
|                           |                       |                      |
| User entered '5 Oct 2020' | Lalicia Roman (b) (4) | 05 Oct 2020 18:05:24 |
|                           | (b) (4)               |                      |



US3802074

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:55:48

[Please select one status for the follow-up contact](#)

| Audit                                      | User                             | Time (GMT)           |
|--|----------------------------------|----------------------|
| Data hard locked.                          | (b) (4), (b) (6)                 | 29 Apr 2021 15:42:08 |
| User signature succeeded.                  | Judith Martin (b) (4)            | 28 Jan 2021 18:19:31 |
| DataPoint Verified.                        | (b) (4)<br>(b) (4), (b) (6)      | 17 Nov 2020 14:55:10 |
| User entered 'Contact Made (CONTACT MADE)' | Lalicia Roman (b) (4)<br>(b) (4) | 05 Oct 2020 18:05:24 |

US3802074

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:55:48

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 29 Apr 2021 15:42:08 |
|                           |                       |                      |
|                           |                       |                      |
| User signature succeeded. | Judith Martin (b) (4) | 28 Jan 2021 18:19:31 |
|                           | (b) (4)               |                      |
| DataPoint Verified.       | (b) (4), (b) (6)      | 17 Nov 2020 14:55:10 |
|                           |                       |                      |
| User entered empty.       | Lalicia Roman (b) (4) | 05 Oct 2020 18:05:24 |
|                           | (b) (4)               |                      |

**US3802074**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:55:48**

[Is the participant continuing to the next visit?](#)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 29 Apr 2021 15:42:08 |
| User signature succeeded. | Judith Martin (b) (4)            | 28 Jan 2021 18:19:31 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)      | 17 Nov 2020 14:55:16 |
| User entered 'Yes (Y)'    | Lalicia Roman (b) (4)<br>(b) (4) | 05 Oct 2020 18:05:32 |

**US3802074**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:55:48**

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:42:08 |
| User entered 'I'  | System           | 05 Oct 2020 18:05:32 |

US3802074

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:55:48

[Was Contact Attempted?](#)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 29 Apr 2021 15:42:08 |
|                           |                                  |                      |
| User signature succeeded. | Judith Martin (b) (4)            | 28 Jan 2021 18:19:31 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)      | 17 Nov 2020 15:03:13 |
| User entered 'Yes (Y)'    | Lalicia Roman (b) (4)<br>(b) (4) | 12 Oct 2020 15:50:59 |

**US3802074**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:55:48**

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

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                 | 29 Apr 2021 15:42:08 |
| User signature succeeded.  | Judith Martin (b) (4)            | 28 Jan 2021 18:19:31 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6)      | 17 Nov 2020 15:03:13 |
| User entered '12 Oct 2020' | Lalicia Roman (b) (4)<br>(b) (4) | 12 Oct 2020 15:50:59 |

US3802074

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:55:48

[Please select one status for the follow-up contact](#)

| Audit                                      | User                             | Time (GMT)           |
|--|----------------------------------|----------------------|
| Data hard locked.                          | (b) (4), (b) (6)                 | 29 Apr 2021 15:42:08 |
| User signature succeeded.                  | Judith Martin (b) (4)            | 28 Jan 2021 18:19:31 |
| DataPoint Verified.                        | (b) (4)<br>(b) (4), (b) (6)      | 17 Nov 2020 15:03:13 |
| User entered 'Contact Made (CONTACT MADE)' | Lalicia Roman (b) (4)<br>(b) (4) | 12 Oct 2020 15:50:59 |

US3802074

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:55:48

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 29 Apr 2021 15:42:08 |
|                           |                       |                      |
|                           |                       |                      |
| User signature succeeded. | Judith Martin (b) (4) | 28 Jan 2021 18:19:31 |
|                           | (b) (4)               |                      |
| DataPoint Verified.       | (b) (4), (b) (6)      | 17 Nov 2020 15:03:13 |
|                           |                       |                      |
|                           |                       |                      |
| User entered empty.       | Lalicia Roman (b) (4) | 12 Oct 2020 15:50:59 |
|                           | (b) (4)               |                      |



US3802074

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:55:48

[Is the participant continuing to the next visit?](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 29 Apr 2021 15:42:08 |
|                           |                       |                      |
| User signature succeeded. | Judith Martin (b) (4) | 28 Jan 2021 18:19:31 |
| DataPoint Verified.       | (b) (4)               |                      |
|                           | (b) (4), (b) (6)      | 17 Nov 2020 15:03:18 |
|                           |                       |                      |
| User entered 'Yes (Y)'    | Lalicia Roman (b) (4) | 12 Oct 2020 15:51:06 |
|                           | (b) (4)               |                      |

**US3802074**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:55:48**

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:42:08 |
|                   |                  |                      |
|                   |                  |                      |
| User entered 'I'  | System           | 12 Oct 2020 15:51:06 |

US3802074

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:55:48

[Was Contact Attempted?](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 29 Apr 2021 15:42:08 |
|                           |                       |                      |
| User signature succeeded. | Judith Martin (b) (4) | 28 Jan 2021 18:19:31 |
| DataPoint Verified.       | (b) (4)               |                      |
|                           | (b) (4), (b) (6)      | 17 Nov 2020 15:04:01 |
|                           |                       |                      |
| User entered 'Yes (Y)'    | Emily Carney (b) (4)  | 19 Oct 2020 15:48:08 |
|                           | (b) (4)               |                      |

US3802074

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:55:48

Date of Contact or Contact Attempt (dd MMM yyyy)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 29 Apr 2021 15:42:08 |
|                            |                       |                      |
| User signature succeeded.  | Judith Martin (b) (4) | 28 Jan 2021 18:19:31 |
| DataPoint Verified.        | (b) (4)               |                      |
|                            | (b) (4), (b) (6)      | 17 Nov 2020 15:04:01 |
|                            |                       |                      |
| User entered '19 Oct 2020' | Emily Carney (b) (4)  | 19 Oct 2020 15:48:08 |
|                            | (b) (4)               |                      |

US3802074

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:55:48

[Please select one status for the follow-up contact](#)

| Audit                                      | User                            | Time (GMT)           |
|--|---------------------------------|----------------------|
| Data hard locked.                          | (b) (4), (b) (6)                | 29 Apr 2021 15:42:08 |
| User signature succeeded.                  | Judith Martin (b) (4)           | 28 Jan 2021 18:19:31 |
| DataPoint Verified.                        | (b) (4)<br>(b) (4), (b) (6)     | 17 Nov 2020 15:04:01 |
| User entered 'Contact Made (CONTACT MADE)' | Emily Carney (b) (4)<br>(b) (4) | 19 Oct 2020 15:48:08 |

US3802074

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:55:48

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 29 Apr 2021 15:42:08 |
|                           |                       |                      |
|                           |                       |                      |
| User signature succeeded. | Judith Martin (b) (4) | 28 Jan 2021 18:19:31 |
|                           | (b) (4)               |                      |
| DataPoint Verified.       | (b) (4), (b) (6)      | 17 Nov 2020 15:04:01 |
|                           |                       |                      |
| User entered empty.       | Emily Carney (b) (4)  | 19 Oct 2020 15:48:08 |
|                           | (b) (4)               |                      |

US3802074

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:55:48

[Is the participant continuing to the next visit?](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 29 Apr 2021 15:42:08 |
|                           |                       |                      |
| User signature succeeded. | Judith Martin (b) (4) | 28 Jan 2021 18:19:31 |
| DataPoint Verified.       | (b) (4)               |                      |
|                           | (b) (4), (b) (6)      | 17 Nov 2020 15:04:07 |
|                           |                       |                      |
| User entered 'Yes (Y)'    | Emily Carney (b) (4)  | 19 Oct 2020 15:48:13 |
|                           | (b) (4)               |                      |

US3802074

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:55:48

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:42:08 |
|                   |                  |                      |
|                   |                  |                      |
| User entered 'I'  | System           | 19 Oct 2020 15:48:13 |



US3802074

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:55:48

[Was this visit performed?](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 29 Apr 2021 15:42:08 |
|                           |                       |                      |
| User signature succeeded. | Judith Martin (b) (4) | 28 Jan 2021 18:19:31 |
| DataPoint Verified.       | (b) (4)               |                      |
|                           | (b) (4), (b) (6)      | 17 Nov 2020 15:21:10 |
|                           |                       |                      |
| User entered 'Yes (Y)'    | Emily Carney (b) (4)  | 22 Oct 2020 12:55:49 |
|                           | (b) (4)               |                      |

US3802074

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:55:48

Visit date (dd MMM yyyy)

| Audit   | User                  | Time (GMT)           |
|---|-----------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)      | 29 Apr 2021 15:42:08 |
|   |                       |                      |
|   |                       |                      |
| User signature succeeded.   | Judith Martin (b) (4) | 28 Jan 2021 18:19:31 |
|   | (b) (4)               |                      |
| DataPoint Verified.   | (b) (4), (b) (6)      | 17 Nov 2020 15:21:10 |
|   |                       |                      |
| User closed query 'Visit 3 Date is < 25 or > 35 days after Visit 2 vaccination. Please reconcile or confirm dates.' (Site from System). |                       | 29 Oct 2020 22:20:31 |
| Query 'Visit 3 Date is < 25 or > 35 days after Visit 2 vaccination. Please reconcile or confirm dates.'                                 | Emily Carney (b) (4)  | 22 Oct 2020 12:57:21 |
| answered with 'Confirm subject came on wrong day so it is out of window' (Site from System).  | (b) (4)               |                      |
| User opened query 'Visit 3 Date is < 25 or > 35 days after Visit 2 vaccination. Please reconcile or confirm dates.' (Site from System). | System                | 22 Oct 2020 12:55:49 |
| User entered '22 Oct 2020'  | Emily Carney (b) (4)  | 22 Oct 2020 12:55:49 |
|   | (b) (4)               |                      |

US3802074

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:55:48

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

| Audit                          | User                            | Time (GMT)           |
|--------------------------------|---------------------------------|----------------------|
| Data hard locked.              | (b) (4), (b) (6)                | 29 Apr 2021 15:42:08 |
| User signature succeeded.      | Judith Martin (b) (4)           | 28 Jan 2021 18:19:31 |
| DataPoint Verified.            | (b) (4)<br>(b) (4), (b) (6)     | 17 Nov 2020 15:21:10 |
| User entered 'Clinic (Clinic)' | Emily Carney (b) (4)<br>(b) (4) | 22 Oct 2020 12:55:49 |

**US3802074**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:55:48**

[Folder OID](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| Data hard locked.     | (b) (4), (b) (6) | 29 Apr 2021 15:42:08 |
| User entered 'VISIT3' | System           | 22 Oct 2020 12:55:49 |

US3802074

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:55:48

[Were vital signs assessed?](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 29 Apr 2021 15:42:08 |
|                           |                       |                      |
| User signature succeeded. | Judith Martin (b) (4) | 28 Jan 2021 18:19:31 |
| DataPoint Verified.       | (b) (4)               |                      |
|                           | (b) (4), (b) (6)      | 17 Nov 2020 15:21:55 |
|                           |                       |                      |
| User entered 'Yes (Y)'    | Emily Carney (b) (4)  | 22 Oct 2020 12:57:56 |
|                           | (b) (4)               |                      |

US3802074

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:55:48

Date of assessment (*dd MMM yyyy*)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 29 Apr 2021 15:42:08 |
|                            |                       |                      |
| User signature succeeded.  | Judith Martin (b) (4) | 28 Jan 2021 18:19:31 |
| DataPoint Verified.        | (b) (4)               |                      |
|                            | (b) (4), (b) (6)      | 17 Nov 2020 15:21:55 |
| User entered '22 Oct 2020' | Emily Carney (b) (4)  | 22 Oct 2020 12:57:56 |
|                            | (b) (4)               |                      |

US3802074

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:55:48

Time of assessment (00:00-23:59)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 29 Apr 2021 15:42:08 |
|                           |                       |                      |
| User signature succeeded. | Judith Martin (b) (4) | 28 Jan 2021 18:19:31 |
| DataPoint Verified.       | (b) (4)               |                      |
|                           | (b) (4), (b) (6)      | 17 Nov 2020 15:21:55 |
|                           |                       |                      |
| User entered '08:22'      | Emily Carney (b) (4)  | 22 Oct 2020 12:57:56 |
|                           | (b) (4)               |                      |

US3802074

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:55:48

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

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 29 Apr 2021 15:42:08 |
|                                  |                  |                      |
|                                  |                  |                      |
| User entered '22 Oct 2020 08:22' | System           | 22 Oct 2020 12:57:56 |



US3802074

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:55:48

Temperature (xxx.x)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 29 Apr 2021 15:42:08 |
|                           |                       |                      |
| User signature succeeded. | Judith Martin (b) (4) | 28 Jan 2021 18:19:31 |
| DataPoint Verified.       | (b) (4)               |                      |
|                           | (b) (4), (b) (6)      | 17 Nov 2020 15:21:55 |
|                           |                       |                      |
| User entered '97.9' F     | Emily Carney (b) (4)  | 22 Oct 2020 12:57:56 |
|                           | (b) (4)               |                      |

US3802074

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:55:48

[Route of measurement](#)

| Audit                        | User                            | Time (GMT)           |
|------------------------------|---------------------------------|----------------------|
| Data hard locked.            | (b) (4), (b) (6)                | 29 Apr 2021 15:42:08 |
| User signature succeeded.    | Judith Martin (b) (4)           | 28 Jan 2021 18:19:31 |
| DataPoint Verified.          | (b) (4)<br>(b) (4), (b) (6)     | 17 Nov 2020 15:21:55 |
| User entered 'Other (Other)' | Emily Carney (b) (4)<br>(b) (4) | 22 Oct 2020 12:57:56 |

US3802074

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:55:48

[If Other, specify](#)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                | 29 Apr 2021 15:42:08 |
| User signature succeeded. | Judith Martin (b) (4)           | 28 Jan 2021 18:19:31 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)     | 17 Nov 2020 15:21:55 |
| User entered 'Infrared'   | Emily Carney (b) (4)<br>(b) (4) | 22 Oct 2020 12:57:56 |

US3802074

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:55:48

[Pulse \(xxx\)](#)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                | 29 Apr 2021 15:42:08 |
|                           |                                 |                      |
| User signature succeeded. | Judith Martin (b) (4)           | 28 Jan 2021 18:19:31 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)     | 17 Nov 2020 15:21:55 |
| User entered '63'         | Emily Carney (b) (4)<br>(b) (4) | 22 Oct 2020 12:57:56 |

**US3802074**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:55:48**

[Pulse units](#)

| Audit              | User             | Time (GMT)           |
|--------------------|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 29 Apr 2021 15:42:08 |
|                    |                  |                      |
|                    |                  |                      |
| User entered 'bpm' | System           | 22 Oct 2020 12:57:56 |

US3802074

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:55:48

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

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 29 Apr 2021 15:42:08 |
|                           |                       |                      |
| User signature succeeded. | Judith Martin (b) (4) | 28 Jan 2021 18:19:31 |
| DataPoint Verified.       | (b) (4)               |                      |
|                           | (b) (4), (b) (6)      | 17 Nov 2020 15:21:55 |
|                           |                       |                      |
| User entered '18'         | Emily Carney (b) (4)  | 22 Oct 2020 12:57:56 |
|                           | (b) (4)               |                      |

**US3802074**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:55:48**

[Respiratory Rate units](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6) | 29 Apr 2021 15:42:08 |
| User entered 'breaths/min' | System           | 22 Oct 2020 12:57:56 |

US3802074

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:55:48

Systolic Blood Pressure (xxx)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 29 Apr 2021 15:42:08 |
|                           |                       |                      |
| User signature succeeded. | Judith Martin (b) (4) | 28 Jan 2021 18:19:31 |
| DataPoint Verified.       | (b) (4)               |                      |
|                           | (b) (4), (b) (6)      | 17 Nov 2020 15:21:55 |
|                           |                       |                      |
| User entered '151'        | Emily Carney (b) (4)  | 22 Oct 2020 12:57:56 |
|                           | (b) (4)               |                      |



US3802074

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:55:48

[Systolic Blood Pressure units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 29 Apr 2021 15:42:08 |
|                     |                  |                      |
|                     |                  |                      |
| User entered 'mmHg' | System           | 22 Oct 2020 12:57:56 |

US3802074

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:55:48

Diastolic Blood Pressure (xxx)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 29 Apr 2021 15:42:08 |
| User signature succeeded. | Judith Martin (b) (4) | 28 Jan 2021 18:19:31 |
| DataPoint Verified.       | (b) (4)               | (b) (4), (b) (6)     |
|                           |                       | 17 Nov 2020 15:21:55 |
| User entered '89'         | Emily Carney (b) (4)  | 22 Oct 2020 12:57:56 |
|                           | (b) (4)               |                      |

**US3802074**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:55:48**

[Diastolic Blood Pressure units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 29 Apr 2021 15:42:08 |
| User entered 'mmHg' | System           | 22 Oct 2020 12:57:56 |

**US3802074**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:55:48**

[Height \(derived\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:42:08 |

**US3802074**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:55:48**

[Weight \(derived\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:42:08 |

US3802074

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:55:48

[Was the physical examination performed?](#)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                | 29 Apr 2021 15:42:08 |
| User signature succeeded. | Judith Martin (b) (4)           | 28 Jan 2021 18:19:31 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)     | 17 Nov 2020 15:22:05 |
| User entered 'No (N)'     | Emily Carney (b) (4)<br>(b) (4) | 22 Oct 2020 12:58:04 |

**US3802074**

**Folder: Visit 3 Day 57 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:55:48**

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

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                | 29 Apr 2021 15:42:08 |
| User signature succeeded. | Judith Martin (b) (4)           | 28 Jan 2021 18:19:31 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)     | 17 Nov 2020 15:22:05 |
| User entered empty.       | Emily Carney (b) (4)<br>(b) (4) | 22 Oct 2020 12:58:04 |

US3802074

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:55:48

[Was the sample collected?](#)

| Audit   | User                  | Time (GMT)           |
|---|-----------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)      | 29 Apr 2021 15:42:08 |
|   |                       |                      |
|   |                       |                      |
| User signature succeeded.   | Judith Martin (b) (4) | 28 Jan 2021 18:19:31 |
|   | (b) (4)               |                      |
| DataPoint Verified.   | (b) (4), (b) (6)      | 17 Nov 2020 15:22:17 |
|   |                       |                      |
| User closed query 'Was the sample collected? is No, however Date and/or Time is present. Please correct.' (Site from System). | System                | 22 Oct 2020 12:58:32 |
| User entered 'Yes (Y)' reason for change: Data Entry Error  | Emily Carney (b) (4)  | 22 Oct 2020 12:58:32 |
|   | (b) (4)               |                      |
| User opened query 'Was the sample collected? is No, however Date and/or Time is present. Please correct.' (Site from System). | System                | 22 Oct 2020 12:58:24 |
| User entered 'No (N)'   | Emily Carney (b) (4)  | 22 Oct 2020 12:58:24 |
|   | (b) (4)               |                      |



**US3802074**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:55:48**

**Collection date** (*dd MMM yyyy*)

| Audit                      | User                            | Time (GMT)           |
|----------------------------|---------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                | 29 Apr 2021 15:42:08 |
| User signature succeeded.  | Judith Martin (b) (4)           | 28 Jan 2021 18:19:31 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6)     | 17 Nov 2020 15:22:17 |
| User entered '22 Oct 2020' | Emily Carney (b) (4)<br>(b) (4) | 22 Oct 2020 12:58:24 |

**US3802074**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:55:48**

[Collection time \(00:00-23:59\)](#)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                | 29 Apr 2021 15:42:08 |
| User signature succeeded. | Judith Martin (b) (4)           | 28 Jan 2021 18:19:31 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)     | 17 Nov 2020 15:22:17 |
| User entered '08:31'      | Emily Carney (b) (4)<br>(b) (4) | 22 Oct 2020 12:58:24 |

**US3802074**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:55:48**

[Collection date and time \(derived\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 29 Apr 2021 15:42:08 |
| User entered '22 Oct 2020 08:31' | System           | 22 Oct 2020 12:58:24 |

US3802074

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:55:48

[Is the participant continuing to the next visit?](#)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                | 29 Apr 2021 15:42:08 |
| User signature succeeded. | Judith Martin (b) (4)           | 28 Jan 2021 18:19:31 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)     | 17 Nov 2020 15:22:24 |
| User entered 'Yes (Y)'    | Emily Carney (b) (4)<br>(b) (4) | 22 Oct 2020 12:58:37 |

**US3802074**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:55:48**

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:42:08 |
| User entered 'I'  | System           | 22 Oct 2020 12:58:37 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

**TIMEPOINT**

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| Data hard locked.     | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| Data entry locked.    | System           | 31 Aug 2020 13:54:40 |
| User entered 'Day 64' | System           | 31 Aug 2020 13:54:40 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

[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)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-10-31T00:01:30', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '93567964-e735-4d0d-b577-0e6d5dca76a8' | System           | 31 Oct 2020 04:02:00 |
| User entered 'No (N)'  | System           | 31 Oct 2020 04:02:00 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

Have you been exposed to someone with 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)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-10-31T00:01:37', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '93567964-e735-4d0d-b577-0e6d5dca76a8' | System           | 31 Oct 2020 04:02:00 |
| User entered 'No (N)'  | System           | 31 Oct 2020 04:02:00 |



**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

[Date and time of submission](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-10-31T00:01:46', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '93567964-e735-4d0d-b577-0e6d5dca76a8' User entered '31 Oct 2020 00:01:46' | System           | 31 Oct 2020 04:02:00 |
|  | System           | 31 Oct 2020 04:02:00 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

[Patient Cloud Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| Data entry locked.               | System           | 31 Aug 2020 13:54:40 |
| User entered '31 Oct 2020 00:01' | System           | 31 Aug 2020 13:54:40 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

[Patient Cloud Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| Data entry locked.               | System           | 31 Aug 2020 13:54:40 |
| User entered '04 Nov 2020 23:59' | System           | 31 Aug 2020 13:54:40 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

**TIMEPOINT**

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| Data hard locked.     | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| Data entry locked.    | System           | 31 Aug 2020 13:54:40 |
| User entered 'Day 71' | System           | 31 Aug 2020 13:54:40 |

US3802074

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:48

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)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-11-07T09:35:12', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '20efc725-e0d7-48b2-985a-edcf0c3955d4' | System           | 07 Nov 2020 14:35:24 |
| User entered 'No (N)'  | System           | 07 Nov 2020 14:35:24 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

Have you been exposed to someone with 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)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-11-07T09:35:16', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '20efc725-e0d7-48b2-985a-edcf0c3955d4' | System           | 07 Nov 2020 14:35:24 |
| User entered 'No (N)'  | System           | 07 Nov 2020 14:35:24 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

[Date and time of submission](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-11-07T09:35:21', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '20efc725-e0d7-48b2-985a-edcf0c3955d4' User entered '07 Nov 2020 09:35:21' | System           | 07 Nov 2020 14:35:24 |
|  | System           | 07 Nov 2020 14:35:24 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

[Patient Cloud Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| Data entry locked.               | System           | 31 Aug 2020 13:54:40 |
| User entered '07 Nov 2020 00:01' | System           | 31 Aug 2020 13:54:40 |



**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

[Patient Cloud Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| Data entry locked.               | System           | 31 Aug 2020 13:54:40 |
| User entered '11 Nov 2020 23:59' | System           | 31 Aug 2020 13:54:40 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

**TIMEPOINT**

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| Data hard locked.     | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| Data entry locked.    | System           | 31 Aug 2020 13:54:40 |
| User entered 'Day 78' | System           | 31 Aug 2020 13:54:40 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

[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)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-11-16T07:22:13', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '85513ce4-f5f4-48eb-923e-9037809c67c6' | System           | 16 Nov 2020 12:22:33 |
| User entered 'No (N)'  | System           | 16 Nov 2020 12:22:33 |

US3802074

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:48

Have you been exposed to someone with 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)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-11-16T07:22:21', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '85513ce4-f5f4-48eb-923e-9037809c67c6' | System           | 16 Nov 2020 12:22:33 |
| User entered 'No (N)'  | System           | 16 Nov 2020 12:22:33 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

[Date and time of submission](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-11-16T07:22:28', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '85513ce4-f5f4-48eb-923e-9037809c67c6' User entered '16 Nov 2020 07:22:28' | System           | 16 Nov 2020 12:22:33 |
|  | System           | 16 Nov 2020 12:22:33 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

[Patient Cloud Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| Data entry locked.               | System           | 31 Aug 2020 13:54:40 |
| User entered '14 Nov 2020 00:01' | System           | 31 Aug 2020 13:54:40 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

[Patient Cloud Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:14:58 |
| Data entry locked.               | System           | 31 Aug 2020 13:54:40 |
| User entered '18 Nov 2020 23:59' | System           | 31 Aug 2020 13:54:40 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

**TIMEPOINT**

| Audit                                    | User   | Time (GMT)           |
|--|--------|----------------------|
| Amendment Manager: Data entry locked.    | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered 'Day 82' | System | 19 Nov 2020 20:44:57 |



**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered '18 Nov 2020 00:01' | System | 19 Nov 2020 20:44:57 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered '22 Nov 2020 23:59' | System | 19 Nov 2020 20:44:57 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

**TIMEPOINT**

| Audit                                    | User   | Time (GMT)           |
|--|--------|----------------------|
| Amendment Manager: Data entry locked.    | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered 'Day 89' | System | 19 Nov 2020 20:44:57 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered '25 Nov 2020 00:01' | System | 19 Nov 2020 20:44:57 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered '29 Nov 2020 23:59' | System | 19 Nov 2020 20:44:57 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

**TIMEPOINT**

| Audit                                    | User   | Time (GMT)           |
|--|--------|----------------------|
| Amendment Manager: Data entry locked.    | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered 'Day 96' | System | 19 Nov 2020 20:44:57 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

[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 (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-12-04T13:53:57', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '002ae70f-d922-461a-93d9-e4de3a7f44c3' | System | 04 Dec 2020 18:54:08 |
| User entered 'No (N)'  | System | 04 Dec 2020 18:54:08 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

Have you been exposed to someone with 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 (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-12-04T13:54:00', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '002ae70f-d922-461a-93d9-e4de3a7f44c3' | System | 04 Dec 2020 18:54:08 |
| User entered 'No (N)'  | System | 04 Dec 2020 18:54:08 |



**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-12-04T13:54:04', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '002ae70f-d922-461a-93d9-e4de3a7f44c3' User entered '04 Dec 2020 13:54:04' | System | 04 Dec 2020 18:54:08 |
|  | System | 04 Dec 2020 18:54:08 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered '02 Dec 2020 00:01' | System | 19 Nov 2020 20:44:57 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered '06 Dec 2020 23:59' | System | 19 Nov 2020 20:44:57 |

**US3802074**

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

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**Generated On: 10 Jun 2021 09:55:48**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered 'Day 103' | System | 19 Nov 2020 20:44:57 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

[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 (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-12-09T08:41:34', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '801760a4-8538-45d5-8623-e47571cbbe9c' | System | 09 Dec 2020 13:41:50 |
| User entered 'No (N)'  | System | 09 Dec 2020 13:41:50 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

Have you been exposed to someone with 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 (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-12-09T08:41:43', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '801760a4-8538-45d5-8623-e47571cbbe9c' | System | 09 Dec 2020 13:41:50 |
| User entered 'No (N)'  | System | 09 Dec 2020 13:41:50 |

**US3802074**

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

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**Generated On: 10 Jun 2021 09:55:48**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-12-09T08:41:48', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '801760a4-8538-45d5-8623-e47571cbbe9c' User entered '09 Dec 2020 08:41:48' | System | 09 Dec 2020 13:41:50 |
|  | System | 09 Dec 2020 13:41:50 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered '09 Dec 2020 00:01' | System | 19 Nov 2020 20:44:57 |



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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 | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered '13 Dec 2020 23:59' | System | 19 Nov 2020 20:44:57 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered 'Day 110' | System | 19 Nov 2020 20:44:57 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

[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 (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-12-19T17:59:44', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '958bdcc6-8bb0-4707-9a1f-3f0ac64a1a00' | System | 19 Dec 2020 22:59:53 |
| User entered 'No (N)'  | System | 19 Dec 2020 22:59:53 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

Have you been exposed to someone with 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 (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-12-19T17:59:47', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '958bdcc6-8bb0-4707-9a1f-3f0ac64a1a00' | System | 19 Dec 2020 22:59:53 |
| User entered 'No (N)'  | System | 19 Dec 2020 22:59:53 |

**US3802074**

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

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[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-12-19T17:59:51', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '958bdcc6-8bb0-4707-9a1f-3f0ac64a1a00' User entered '19 Dec 2020 17:59:51' | System | 19 Dec 2020 22:59:53 |
|  | System | 19 Dec 2020 22:59:53 |

**US3802074**

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

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**Generated On: 10 Jun 2021 09:55:48**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered '16 Dec 2020 00:01' | System | 19 Nov 2020 20:44:57 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered '20 Dec 2020 23:59' | System | 19 Nov 2020 20:44:57 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered 'Day 117' | System | 19 Nov 2020 20:44:57 |



**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

[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 (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-12-25T23:10:30', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '9ef44ff0-17a3-4375-8b67-fe05188cf63c' | System | 26 Dec 2020 04:10:41 |
| User entered 'No (N)'  | System | 26 Dec 2020 04:10:41 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

Have you been exposed to someone with 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 (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-12-25T23:10:34', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '9ef44ff0-17a3-4375-8b67-fe05188cf63c' | System | 26 Dec 2020 04:10:41 |
| User entered 'No (N)'  | System | 26 Dec 2020 04:10:41 |

**US3802074**

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

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| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2020-12-25T23:10:38', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '9ef44ff0-17a3-4375-8b67-fe05188cf63c' User entered '25 Dec 2020 23:10:38' | System | 26 Dec 2020 04:10:41 |
|  | System | 26 Dec 2020 04:10:41 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered '23 Dec 2020 00:01' | System | 19 Nov 2020 20:44:57 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered '27 Dec 2020 23:59' | System | 19 Nov 2020 20:44:57 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered 'Day 124' | System | 19 Nov 2020 20:44:57 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

[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 (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2021-01-01T12:02:28', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '279e3177-b196-427a-8674-be5c7c49408e' | System | 01 Jan 2021 17:02:40 |
| User entered 'No (N)'  | System | 01 Jan 2021 17:02:40 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

Have you been exposed to someone with 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 (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2021-01-01T12:02:34', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '279e3177-b196-427a-8674-be5c7c49408e' | System | 01 Jan 2021 17:02:40 |
| User entered 'No (N)'  | System | 01 Jan 2021 17:02:40 |



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| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2021-01-01T12:02:38', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '279e3177-b196-427a-8674-be5c7c49408e' User entered '01 Jan 2021 12:02:38' | System | 01 Jan 2021 17:02:40 |

**US3802074**

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**Generated On: 10 Jun 2021 09:55:48**

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered '30 Dec 2020 00:01' | System | 19 Nov 2020 20:44:57 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered '03 Jan 2021 23:59' | System | 19 Nov 2020 20:44:57 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered 'Day 131' | System | 19 Nov 2020 20:44:57 |

**US3802074**

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

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[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 (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2021-01-06T23:20:28', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '42a4905b-d0d2-42b7-9db1-b3b68cdb7c55' | System | 07 Jan 2021 04:20:37 |
| User entered 'No (N)'  | System | 07 Jan 2021 04:20:37 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

Have you been exposed to someone with 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 (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2021-01-06T23:20:31', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '42a4905b-d0d2-42b7-9db1-b3b68cdb7c55' | System | 07 Jan 2021 04:20:37 |
| User entered 'No (N)'  | System | 07 Jan 2021 04:20:37 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2021-01-06T23:20:35', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '42a4905b-d0d2-42b7-9db1-b3b68cdb7c55' | System | 07 Jan 2021 04:20:37 |
| User entered '06 Jan 2021 23:20:35'  | System | 07 Jan 2021 04:20:37 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered '06 Jan 2021 00:01' | System | 19 Nov 2020 20:44:57 |



**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered '10 Jan 2021 23:59' | System | 19 Nov 2020 20:44:57 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered 'Day 138' | System | 19 Nov 2020 20:44:57 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

[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 (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2021-01-15T12:00:51', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '5fba55a2-2513-4650-855f-422467c01787' | System | 22 Jan 2021 18:54:49 |
| User entered 'No (N)'  | System | 22 Jan 2021 18:54:49 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

Have you been exposed to someone with 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 (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2021-01-15T12:00:57', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '5fba55a2-2513-4650-855f-422467c01787' | System | 22 Jan 2021 18:54:49 |
| User entered 'Yes (Y)'   | System | 22 Jan 2021 18:54:49 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

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

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2021-01-15T12:01:08', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '5fba55a2-2513-4650-855f-422467c01787' | System | 22 Jan 2021 18:54:49 |
| User entered 'I confirm I have read this message and will call the study clinic immediately (9)'   | System | 22 Jan 2021 18:54:49 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2021-01-15T12:01:12', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '5fba55a2-2513-4650-855f-422467c01787' User entered '15 Jan 2021 12:01:12' | System | 22 Jan 2021 18:54:49 |
|  | System | 22 Jan 2021 18:54:49 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered '13 Jan 2021 00:01' | System | 19 Nov 2020 20:44:57 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered '17 Jan 2021 23:59' | System | 19 Nov 2020 20:44:57 |



**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered 'Day 145' | System | 19 Nov 2020 20:44:57 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

[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 (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2021-01-22T13:54:46', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '6b82ad0a-c1d9-422f-941c-86e98df33911' | System | 22 Jan 2021 18:55:04 |
| User entered 'No (N)'  | System | 22 Jan 2021 18:55:04 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

Have you been exposed to someone with 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 (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2021-01-22T13:54:54', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '6b82ad0a-c1d9-422f-941c-86e98df33911' | System | 22 Jan 2021 18:55:04 |
| User entered 'No (N)'  | System | 22 Jan 2021 18:55:04 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2021-01-22T13:54:59', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '6b82ad0a-c1d9-422f-941c-86e98df33911' User entered '22 Jan 2021 13:54:59' | System | 22 Jan 2021 18:55:04 |
|  | System | 22 Jan 2021 18:55:04 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered '20 Jan 2021 00:01' | System | 19 Nov 2020 20:44:57 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered '24 Jan 2021 23:59' | System | 19 Nov 2020 20:44:57 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered 'Day 152' | System | 19 Nov 2020 20:44:57 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

[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 (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2021-01-27T08:55:43', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: 'a679a42d-fb15-4bbf-a0dc-381a844843c3' User entered 'No (N)' | System | 27 Jan 2021 13:55:53 |
|  | System | 27 Jan 2021 13:55:53 |



**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

[Have you been exposed to someone with 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 (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2021-01-27T08:55:47', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: 'a679a42d-fb15-4bbf-a0dc-381a844843c3' User entered 'No (N)' | System | 27 Jan 2021 13:55:53 |
|  | System | 27 Jan 2021 13:55:53 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2021-01-27T08:55:51', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: 'a679a42d-fb15-4bbf-a0dc-381a844843c3' User entered '27 Jan 2021 08:55:51' | System | 27 Jan 2021 13:55:53 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered '27 Jan 2021 00:01' | System | 19 Nov 2020 20:44:57 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered '31 Jan 2021 23:59' | System | 19 Nov 2020 20:44:57 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered 'Day 159' | System | 19 Nov 2020 20:44:57 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

[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 (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2021-02-05T12:00:41', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: 'becc9fcc-9d3f-402c-8e16-81a3befe2771' User entered 'No (N)' | System | 05 Feb 2021 17:03:08 |
|  | System | 05 Feb 2021 17:03:08 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

Have you been exposed to someone with 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 (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2021-02-05T12:00:44', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: 'becc9fcc-9d3f-402c-8e16-81a3befe2771' User entered 'No (N)' | System | 05 Feb 2021 17:03:08 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2021-02-05T12:00:49', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: 'becc9fcc-9d3f-402c-8e16-81a3befe2771' User entered '05 Feb 2021 12:00:49' | System | 05 Feb 2021 17:03:08 |



**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered '03 Feb 2021 00:01' | System | 19 Nov 2020 20:44:57 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered '07 Feb 2021 23:59' | System | 19 Nov 2020 20:44:57 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered 'Day 166' | System | 19 Nov 2020 20:44:57 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

[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 (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2021-02-10T21:10:04', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '68ccbf06-f056-443f-b93c-67b5c8f59354' | System | 11 Feb 2021 02:20:04 |
| User entered 'No (N)'  | System | 11 Feb 2021 02:20:04 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

Have you been exposed to someone with 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 (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2021-02-10T21:10:17', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '68ccbf06-f056-443f-b93c-67b5c8f59354' | System | 11 Feb 2021 02:20:04 |
| User entered 'No (N)'  | System | 11 Feb 2021 02:20:04 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2021-02-10T21:10:24', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '68ccbf06-f056-443f-b93c-67b5c8f59354' User entered '10 Feb 2021 21:10:24' | System | 11 Feb 2021 02:20:04 |
|  | System | 11 Feb 2021 02:20:04 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered '10 Feb 2021 00:01' | System | 19 Nov 2020 20:44:57 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered '14 Feb 2021 23:59' | System | 19 Nov 2020 20:44:57 |



**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered 'Day 173' | System | 19 Nov 2020 20:44:57 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

[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 (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2021-02-17T07:32:46', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '034001f2-17da-4e3c-9521-beec22ec3dfc' User entered 'No (N)' | System | 17 Feb 2021 12:32:55 |
|  | System | 17 Feb 2021 12:32:55 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

Have you been exposed to someone with 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 (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2021-02-17T07:32:49', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '034001f2-17da-4e3c-9521-beec22ec3dfc' | System | 17 Feb 2021 12:32:55 |
| User entered 'No (N)'  | System | 17 Feb 2021 12:32:55 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2021-02-17T07:32:53', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '034001f2-17da-4e3c-9521-beec22ec3dfc' User entered '17 Feb 2021 07:32:53' | System | 17 Feb 2021 12:32:55 |
|  | System | 17 Feb 2021 12:32:55 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered '17 Feb 2021 00:01' | System | 19 Nov 2020 20:44:57 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered '21 Feb 2021 23:59' | System | 19 Nov 2020 20:44:57 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered 'Day 180' | System | 19 Nov 2020 20:44:57 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

[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 (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2021-02-24T06:25:36-05:00', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: 'f757eabf-06ff-410a-bdc0-0b7b0f81a7bf' | System | 24 Feb 2021 11:25:50 |
| User entered 'No (N)'  | System | 24 Feb 2021 11:25:50 |



**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

Have you been exposed to someone with 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 (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2021-02-24T06:25:43-05:00', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: 'f757eabf-06ff-410a-bdc0-0b7b0f81a7bf' | System | 24 Feb 2021 11:25:50 |
| User entered 'No (N)'  | System | 24 Feb 2021 11:25:50 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2021-02-24T06:25:48-05:00', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: 'f757eabf-06ff-410a-bdc0-0b7b0f81a7bf' User entered '24 Feb 2021 11:25:48' | System | 24 Feb 2021 11:25:50 |
|  | System | 24 Feb 2021 11:25:50 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered '24 Feb 2021 00:01' | System | 19 Nov 2020 20:44:57 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered '28 Feb 2021 23:59' | System | 19 Nov 2020 20:44:57 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered 'Day 187' | System | 19 Nov 2020 20:44:57 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

[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 (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2021-03-07T12:19:56-05:00', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '8fff4455-4910-41e2-8ad1-5fde19a6ffe8' | System | 07 Mar 2021 17:20:07 |
| User entered 'No (N)'  | System | 07 Mar 2021 17:20:07 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

Have you been exposed to someone with 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 (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2021-03-07T12:19:59-05:00', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '8fff4455-4910-41e2-8ad1-5fde19a6ffe8' | System | 07 Mar 2021 17:20:07 |
| User entered 'No (N)'  | System | 07 Mar 2021 17:20:07 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2021-03-07T12:20:02-05:00', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '8fff4455-4910-41e2-8ad1-5fde19a6ffe8' User entered '07 Mar 2021 12:20:02' | System | 07 Mar 2021 17:20:07 |
|  | System | 07 Mar 2021 17:20:07 |



**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered '03 Mar 2021 00:01' | System | 19 Nov 2020 20:44:57 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered '07 Mar 2021 23:59' | System | 19 Nov 2020 20:44:57 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered 'Day 194' | System | 19 Nov 2020 20:44:57 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

[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 (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2021-03-12T11:30:57-05:00', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '51d3e989-0ae8-4b7d-b7d4-38fc26f1e2c4' | System | 12 Mar 2021 16:31:08 |
| User entered 'No (N)'  | System | 12 Mar 2021 16:31:08 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

Have you been exposed to someone with 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 (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2021-03-12T11:31:00-05:00', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '51d3e989-0ae8-4b7d-b7d4-38fc26f1e2c4' | System | 12 Mar 2021 16:31:08 |
| User entered 'No (N)'  | System | 12 Mar 2021 16:31:08 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2021-03-12T11:31:03-05:00', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '51d3e989-0ae8-4b7d-b7d4-38fc26f1e2c4' | System | 12 Mar 2021 16:31:08 |
| User entered '12 Mar 2021 11:31:03'  | System | 12 Mar 2021 16:31:08 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered '10 Mar 2021 00:01' | System | 19 Nov 2020 20:44:57 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered '14 Mar 2021 23:59' | System | 19 Nov 2020 20:44:57 |



**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered 'Day 201' | System | 19 Nov 2020 20:44:57 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

[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 (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2021-03-17T20:50:05-04:00', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: 'e3c7c0a2-7c0c-431d-a4ba-8d35cb924c7c' | System | 18 Mar 2021 00:50:27 |
| User entered 'Yes (Y)'   | System | 18 Mar 2021 00:50:27 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

Have you been exposed to someone with 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 (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2021-03-17T20:50:09-04:00', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: 'e3c7c0a2-7c0c-431d-a4ba-8d35cb924c7c' | System | 18 Mar 2021 00:50:27 |
| User entered 'No (N)'  | System | 18 Mar 2021 00:50:27 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2021-03-17T20:50:15-04:00', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: 'e3c7c0a2-7c0c-431d-a4ba-8d35cb924c7c' | System | 18 Mar 2021 00:50:27 |
| User entered 'No (N)'  | System | 18 Mar 2021 00:50:27 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2021-03-17T20:50:19-04:00', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: 'e3c7c0a2-7c0c-431d-a4ba-8d35cb924c7c' | System | 18 Mar 2021 00:50:27 |
| User entered 'No (N)'  | System | 18 Mar 2021 00:50:27 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2021-03-17T20:50:24-04:00', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: 'e3c7c0a2-7c0c-431d-a4ba-8d35cb924c7c' User entered '17 Mar 2021 20:50:24' | System | 18 Mar 2021 00:50:27 |
|  | System | 18 Mar 2021 00:50:27 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered '17 Mar 2021 00:01' | System | 19 Nov 2020 20:44:57 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered '21 Mar 2021 23:59' | System | 19 Nov 2020 20:44:57 |



**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered 'Day 208' | System | 19 Nov 2020 20:44:57 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

[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 (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2021-03-26T12:00:58-04:00', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '359c6e2d-b0f0-4fda-a12a-acc035ec8772' | System | 26 Mar 2021 16:03:29 |
| User entered 'No (N)'  | System | 26 Mar 2021 16:03:29 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

Have you been exposed to someone with 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 (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2021-03-26T12:01:07-04:00', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '359c6e2d-b0f0-4fda-a12a-acc035ec8772' | System | 26 Mar 2021 16:03:29 |
| User entered 'No (N)'  | System | 26 Mar 2021 16:03:29 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2021-03-26T12:01:12-04:00', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '359c6e2d-b0f0-4fda-a12a-acc035ec8772' | System | 26 Mar 2021 16:03:29 |
| User entered '26 Mar 2021 12:01:12'  | System | 26 Mar 2021 16:03:29 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered '24 Mar 2021 00:01' | System | 19 Nov 2020 20:44:57 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered '28 Mar 2021 23:59' | System | 19 Nov 2020 20:44:57 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered 'Day 215' | System | 19 Nov 2020 20:44:57 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

[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 (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2021-03-31T07:01:28-04:00', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '79d61444-aa14-4276-8a37-f731f9ec4899' | System | 31 Mar 2021 11:02:21 |
| User entered 'Yes (Y)'   | System | 31 Mar 2021 11:02:21 |



**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

[Have you been exposed to someone with 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 (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2021-03-31T07:01:31-04:00', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '79d61444-aa14-4276-8a37-f731f9ec4899' | System | 31 Mar 2021 11:02:21 |
| User entered 'No (N)'  | System | 31 Mar 2021 11:02:21 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2021-03-31T07:01:36-04:00', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '79d61444-aa14-4276-8a37-f731f9ec4899' | System | 31 Mar 2021 11:02:21 |
| User entered 'No (N)'  | System | 31 Mar 2021 11:02:21 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2021-03-31T07:01:43-04:00', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '79d61444-aa14-4276-8a37-f731f9ec4899' | System | 31 Mar 2021 11:02:21 |
| User entered 'Yes (Y)'   | System | 31 Mar 2021 11:02:21 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

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

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2021-03-31T07:01:59-04:00', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '79d61444-aa14-4276-8a37-f731f9ec4899' | System | 31 Mar 2021 11:02:21 |
| User entered 'I confirm I have read this message and will call the study clinic immediately (9)'   | System | 31 Mar 2021 11:02:21 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2021-03-31T07:02:08-04:00', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '79d61444-aa14-4276-8a37-f731f9ec4899' | System | 31 Mar 2021 11:02:21 |
| User entered '31 Mar 2021 07:02:08'  | System | 31 Mar 2021 11:02:21 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered '31 Mar 2021 00:01' | System | 19 Nov 2020 20:44:57 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered '04 Apr 2021 23:59' | System | 19 Nov 2020 20:44:57 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered 'Day 222' | System | 19 Nov 2020 20:44:57 |



**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

[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 (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2021-04-07T06:25:16-04:00', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '5795f64b-cee8-4258-a623-4908bec00fc1' User entered 'No (N)' | System | 07 Apr 2021 10:25:25 |
|  | System | 07 Apr 2021 10:25:25 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

Have you been exposed to someone with 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 (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2021-04-07T06:25:19-04:00', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '5795f64b-cee8-4258-a623-4908bec00fc1' | System | 07 Apr 2021 10:25:25 |
| User entered 'No (N)'  | System | 07 Apr 2021 10:25:25 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2021-04-07T06:25:22-04:00', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '5795f64b-cee8-4258-a623-4908bec00fc1' User entered '07 Apr 2021 06:25:22' | System | 07 Apr 2021 10:25:25 |
|  | System | 07 Apr 2021 10:25:25 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered '07 Apr 2021 00:01' | System | 19 Nov 2020 20:44:57 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered '11 Apr 2021 23:59' | System | 19 Nov 2020 20:44:57 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered 'Day 229' | System | 19 Nov 2020 20:44:57 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

[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 (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2021-04-14T07:38:08-04:00', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '7c33ac70-df37-420c-a533-0f4997e19b09' | System | 14 Apr 2021 11:38:16 |
| User entered 'No (N)'  | System | 14 Apr 2021 11:38:16 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

Have you been exposed to someone with 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 (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2021-04-14T07:38:10-04:00', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '7c33ac70-df37-420c-a533-0f4997e19b09' | System | 14 Apr 2021 11:38:16 |
| User entered 'No (N)'  | System | 14 Apr 2021 11:38:16 |



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

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**Generated On: 10 Jun 2021 09:55:48**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2021-04-14T07:38:13-04:00', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '7c33ac70-df37-420c-a533-0f4997e19b09' | System | 14 Apr 2021 11:38:16 |
| User entered '14 Apr 2021 07:38:13'  | System | 14 Apr 2021 11:38:16 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered '14 Apr 2021 00:01' | System | 19 Nov 2020 20:44:57 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered '18 Apr 2021 23:59' | System | 19 Nov 2020 20:44:57 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered 'Day 236' | System | 19 Nov 2020 20:44:57 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

[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 (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2021-04-24T17:12:44-04:00', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '00e1aa62-2633-41ff-b205-cb134e366978' | System | 24 Apr 2021 21:13:04 |
| User entered 'Yes (Y)'   | System | 24 Apr 2021 21:13:04 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

Have you been exposed to someone with 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 (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2021-04-24T17:12:48-04:00', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '00e1aa62-2633-41ff-b205-cb134e366978' User entered 'No (N)' | System | 24 Apr 2021 21:13:04 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2021-04-24T17:12:53-04:00', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '00e1aa62-2633-41ff-b205-cb134e366978' User entered 'No (N)' | System | 24 Apr 2021 21:13:04 |
|  | System | 24 Apr 2021 21:13:04 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2021-04-24T17:12:57-04:00', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '00e1aa62-2633-41ff-b205-cb134e366978' | System | 24 Apr 2021 21:13:04 |
| User entered 'No (N)'  | System | 24 Apr 2021 21:13:04 |



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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2021-04-24T17:13:02-04:00', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '00e1aa62-2633-41ff-b205-cb134e366978' User entered '24 Apr 2021 17:13:02' | System | 24 Apr 2021 21:13:04 |
|  | System | 24 Apr 2021 21:13:04 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered '21 Apr 2021 00:01' | System | 19 Nov 2020 20:44:57 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered '25 Apr 2021 23:59' | System | 19 Nov 2020 20:44:57 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered 'Day 243' | System | 19 Nov 2020 20:44:57 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

[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 (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2021-04-29T10:54:25-04:00', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '5ff1f866-ab39-4ef4-a74e-880ed07c1db4' | System | 29 Apr 2021 15:15:19 |
| User entered 'No (N)'  | System | 29 Apr 2021 15:15:19 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

Have you been exposed to someone with 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 (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2021-04-29T10:54:27-04:00', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '5ff1f866-ab39-4ef4-a74e-880ed07c1db4' | System | 29 Apr 2021 15:15:19 |
| User entered 'No (N)'  | System | 29 Apr 2021 15:15:19 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2021-04-29T10:54:30-04:00', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: '5ff1f866-ab39-4ef4-a74e-880ed07c1db4' | System | 29 Apr 2021 15:15:19 |
| User entered '29 Apr 2021 10:54:30'  | System | 29 Apr 2021 15:15:19 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered '28 Apr 2021 00:01' | System | 19 Nov 2020 20:44:57 |



**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered '02 May 2021 23:59' | System | 19 Nov 2020 20:44:57 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered 'Day 250' | System | 19 Nov 2020 20:44:57 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered '05 May 2021 00:01' | System | 19 Nov 2020 20:44:57 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered '09 May 2021 23:59' | System | 19 Nov 2020 20:44:57 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered 'Day 257' | System | 19 Nov 2020 20:44:57 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered '12 May 2021 00:01' | System | 19 Nov 2020 20:44:57 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered '16 May 2021 23:59' | System | 19 Nov 2020 20:44:57 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered 'Day 264' | System | 19 Nov 2020 20:44:57 |



**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered '19 May 2021 00:01' | System | 19 Nov 2020 20:44:57 |

**US3802074**

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

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**Generated On: 10 Jun 2021 09:55:48**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered '23 May 2021 23:59' | System | 19 Nov 2020 20:44:57 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered 'Day 271' | System | 19 Nov 2020 20:44:57 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered '26 May 2021 00:01' | System | 19 Nov 2020 20:44:57 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered '30 May 2021 23:59' | System | 19 Nov 2020 20:44:57 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered 'Day 278' | System | 19 Nov 2020 20:44:57 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered '02 Jun 2021 00:01' | System | 19 Nov 2020 20:44:57 |

**US3802074**

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

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**Generated On: 10 Jun 2021 09:55:48**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered '06 Jun 2021 23:59' | System | 19 Nov 2020 20:44:57 |



**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered 'Day 285' | System | 19 Nov 2020 20:44:57 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered '09 Jun 2021 00:01' | System | 19 Nov 2020 20:44:57 |

**US3802074**

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

**Form: Safety Follow Up Diary**

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[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered '13 Jun 2021 23:59' | System | 19 Nov 2020 20:44:57 |

**US3802074**

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

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**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered 'Day 292' | System | 19 Nov 2020 20:44:57 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered '16 Jun 2021 00:01' | System | 19 Nov 2020 20:44:57 |

**US3802074**

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

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**Generated On: 10 Jun 2021 09:55:48**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered '20 Jun 2021 23:59' | System | 19 Nov 2020 20:44:57 |

**US3802074**

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

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**Generated On: 10 Jun 2021 09:55:48**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered 'Day 299' | System | 19 Nov 2020 20:44:57 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered '23 Jun 2021 00:01' | System | 19 Nov 2020 20:44:57 |



**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered '27 Jun 2021 23:59' | System | 19 Nov 2020 20:44:57 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered 'Day 306' | System | 19 Nov 2020 20:44:57 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered '30 Jun 2021 00:01' | System | 19 Nov 2020 20:44:57 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered '04 Jul 2021 23:59' | System | 19 Nov 2020 20:44:57 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered 'Day 313' | System | 19 Nov 2020 20:44:57 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered '07 Jul 2021 00:01' | System | 19 Nov 2020 20:44:57 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered '11 Jul 2021 23:59' | System | 19 Nov 2020 20:44:57 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered 'Day 320' | System | 19 Nov 2020 20:44:57 |



**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered '14 Jul 2021 00:01' | System | 19 Nov 2020 20:44:57 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered '18 Jul 2021 23:59' | System | 19 Nov 2020 20:44:57 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered 'Day 327' | System | 19 Nov 2020 20:44:57 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered '21 Jul 2021 00:01' | System | 19 Nov 2020 20:44:57 |

**US3802074**

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

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**Generated On: 10 Jun 2021 09:55:48**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered '25 Jul 2021 23:59' | System | 19 Nov 2020 20:44:57 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered 'Day 334' | System | 19 Nov 2020 20:44:57 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered '28 Jul 2021 00:01' | System | 19 Nov 2020 20:44:57 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered '01 Aug 2021 23:59' | System | 19 Nov 2020 20:44:57 |



**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered 'Day 341' | System | 19 Nov 2020 20:44:57 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered '04 Aug 2021 00:01' | System | 19 Nov 2020 20:44:57 |

**US3802074**

**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 | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered '08 Aug 2021 23:59' | System | 19 Nov 2020 20:44:57 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered 'Day 348' | System | 19 Nov 2020 20:44:57 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered '11 Aug 2021 00:01' | System | 19 Nov 2020 20:44:57 |

**US3802074**

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

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**Generated On: 10 Jun 2021 09:55:48**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered '15 Aug 2021 23:59' | System | 19 Nov 2020 20:44:57 |

**US3802074**

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

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**Generated On: 10 Jun 2021 09:55:48**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered 'Day 355' | System | 19 Nov 2020 20:44:57 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered '18 Aug 2021 00:01' | System | 19 Nov 2020 20:44:57 |



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

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered '22 Aug 2021 23:59' | System | 19 Nov 2020 20:44:57 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered 'Day 362' | System | 19 Nov 2020 20:44:57 |

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

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered '25 Aug 2021 00:01' | System | 19 Nov 2020 20:44:57 |

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

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered '29 Aug 2021 23:59' | System | 19 Nov 2020 20:44:57 |

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

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**Generated On: 10 Jun 2021 09:55:48**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered 'Day 369' | System | 19 Nov 2020 20:44:57 |

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**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 | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered '01 Sep 2021 00:01' | System | 19 Nov 2020 20:44:57 |

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

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered '05 Sep 2021 23:59' | System | 19 Nov 2020 20:44:57 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered 'Day 376' | System | 19 Nov 2020 20:44:57 |



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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered '08 Sep 2021 00:01' | System | 19 Nov 2020 20:44:57 |

**US3802074**

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

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**Generated On: 10 Jun 2021 09:55:48**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered '12 Sep 2021 23:59' | System | 19 Nov 2020 20:44:57 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered 'Day 383' | System | 19 Nov 2020 20:44:57 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered '15 Sep 2021 00:01' | System | 19 Nov 2020 20:44:57 |

**US3802074**

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

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**Generated On: 10 Jun 2021 09:55:48**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered '19 Sep 2021 23:59' | System | 19 Nov 2020 20:44:57 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered 'Day 390' | System | 19 Nov 2020 20:44:57 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered '22 Sep 2021 00:01' | System | 19 Nov 2020 20:44:57 |

**US3802074**

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

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered '26 Sep 2021 23:59' | System | 19 Nov 2020 20:44:57 |



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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered 'Day 397' | System | 19 Nov 2020 20:44:57 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered '29 Sep 2021 00:01' | System | 19 Nov 2020 20:44:57 |

**US3802074**

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

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered '03 Oct 2021 23:59' | System | 19 Nov 2020 20:44:57 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered 'Day 404' | System | 19 Nov 2020 20:44:57 |

**US3802074**

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

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**Generated On: 10 Jun 2021 09:55:48**

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered '06 Oct 2021 00:01' | System | 19 Nov 2020 20:44:57 |

**US3802074**

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

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**Generated On: 10 Jun 2021 09:55:48**

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered '10 Oct 2021 23:59' | System | 19 Nov 2020 20:44:57 |

**US3802074**

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

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**Generated On: 10 Jun 2021 09:55:48**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered 'Day 411' | System | 19 Nov 2020 20:44:57 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered '13 Oct 2021 00:01' | System | 19 Nov 2020 20:44:57 |



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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered '17 Oct 2021 23:59' | System | 19 Nov 2020 20:44:57 |

**US3802074**

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

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**Generated On: 10 Jun 2021 09:55:48**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered 'Day 418' | System | 19 Nov 2020 20:44:57 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered '20 Oct 2021 00:01' | System | 19 Nov 2020 20:44:57 |

**US3802074**

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

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered '24 Oct 2021 23:59' | System | 19 Nov 2020 20:44:57 |

**US3802074**

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

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**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered 'Day 425' | System | 19 Nov 2020 20:44:57 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered '27 Oct 2021 00:01' | System | 19 Nov 2020 20:44:57 |

**US3802074**

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

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered '31 Oct 2021 23:59' | System | 19 Nov 2020 20:44:57 |

**US3802074**

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

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**Generated On: 10 Jun 2021 09:55:48**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered 'Day 432' | System | 19 Nov 2020 20:44:57 |



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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered '03 Nov 2021 00:01' | System | 19 Nov 2020 20:44:57 |

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

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered '07 Nov 2021 23:59' | System | 19 Nov 2020 20:44:57 |

**US3802074**

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

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**Generated On: 10 Jun 2021 09:55:48**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered 'Day 439' | System | 19 Nov 2020 20:44:57 |

**US3802074**

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

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**Generated On: 10 Jun 2021 09:55:48**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered '10 Nov 2021 00:01' | System | 19 Nov 2020 20:44:57 |

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

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered '14 Nov 2021 23:59' | System | 19 Nov 2020 20:44:57 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered 'Day 446' | System | 19 Nov 2020 20:44:57 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered '17 Nov 2021 00:01' | System | 19 Nov 2020 20:44:57 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered '21 Nov 2021 23:59' | System | 19 Nov 2020 20:44:57 |



**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered 'Day 453' | System | 19 Nov 2020 20:44:57 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered '24 Nov 2021 00:01' | System | 19 Nov 2020 20:44:57 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered '28 Nov 2021 23:59' | System | 19 Nov 2020 20:44:57 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered 'Day 460' | System | 19 Nov 2020 20:44:57 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered '01 Dec 2021 00:01' | System | 19 Nov 2020 20:44:57 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered '05 Dec 2021 23:59' | System | 19 Nov 2020 20:44:57 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered 'Day 467' | System | 19 Nov 2020 20:44:57 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered '08 Dec 2021 00:01' | System | 19 Nov 2020 20:44:57 |



**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered '12 Dec 2021 23:59' | System | 19 Nov 2020 20:44:57 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered 'Day 474' | System | 19 Nov 2020 20:44:57 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered '15 Dec 2021 00:01' | System | 19 Nov 2020 20:44:57 |

**US3802074**

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

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**Generated On: 10 Jun 2021 09:55:48**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered '19 Dec 2021 23:59' | System | 19 Nov 2020 20:44:57 |

**US3802074**

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

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**Generated On: 10 Jun 2021 09:55:48**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered 'Day 481' | System | 19 Nov 2020 20:44:57 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered '22 Dec 2021 00:01' | System | 19 Nov 2020 20:44:57 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered '26 Dec 2021 23:59' | System | 19 Nov 2020 20:44:57 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered 'Day 488' | System | 19 Nov 2020 20:44:57 |



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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered '29 Dec 2021 00:01' | System | 19 Nov 2020 20:44:57 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered '02 Jan 2022 23:59' | System | 19 Nov 2020 20:44:57 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered 'Day 495' | System | 19 Nov 2020 20:44:57 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered '05 Jan 2022 00:01' | System | 19 Nov 2020 20:44:57 |

**US3802074**

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

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**Generated On: 10 Jun 2021 09:55:48**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered '09 Jan 2022 23:59' | System | 19 Nov 2020 20:44:57 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered 'Day 502' | System | 19 Nov 2020 20:44:57 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered '12 Jan 2022 00:01' | System | 19 Nov 2020 20:44:57 |

**US3802074**

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

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**Generated On: 10 Jun 2021 09:55:48**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered '16 Jan 2022 23:59' | System | 19 Nov 2020 20:44:57 |



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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered 'Day 509' | System | 19 Nov 2020 20:44:57 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered '19 Jan 2022 00:01' | System | 19 Nov 2020 20:44:57 |

**US3802074**

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

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**Generated On: 10 Jun 2021 09:55:48**

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered '23 Jan 2022 23:59' | System | 19 Nov 2020 20:44:57 |

**US3802074**

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

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**Generated On: 10 Jun 2021 09:55:48**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered 'Day 516' | System | 19 Nov 2020 20:44:57 |

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered '26 Jan 2022 00:01' | System | 19 Nov 2020 20:44:57 |

**US3802074**

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

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**Generated On: 10 Jun 2021 09:55:48**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered '30 Jan 2022 23:59' | System | 19 Nov 2020 20:44:57 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered 'Day 523' | System | 19 Nov 2020 20:44:57 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered '02 Feb 2022 00:01' | System | 19 Nov 2020 20:44:57 |



**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered '06 Feb 2022 23:59' | System | 19 Nov 2020 20:44:57 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered 'Day 530' | System | 19 Nov 2020 20:44:57 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered '09 Feb 2022 00:01' | System | 19 Nov 2020 20:44:57 |

**US3802074**

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

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**Generated On: 10 Jun 2021 09:55:48**

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered '13 Feb 2022 23:59' | System | 19 Nov 2020 20:44:57 |

**US3802074**

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

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**Generated On: 10 Jun 2021 09:55:48**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered 'Day 537' | System | 19 Nov 2020 20:44:57 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered '16 Feb 2022 00:01' | System | 19 Nov 2020 20:44:57 |

**US3802074**

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

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered '20 Feb 2022 23:59' | System | 19 Nov 2020 20:44:57 |

**US3802074**

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

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**Generated On: 10 Jun 2021 09:55:48**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered 'Day 544' | System | 19 Nov 2020 20:44:57 |



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

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**Generated On: 10 Jun 2021 09:55:48**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered '23 Feb 2022 00:01' | System | 19 Nov 2020 20:44:57 |

**US3802074**

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

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**Generated On: 10 Jun 2021 09:55:48**

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered '27 Feb 2022 23:59' | System | 19 Nov 2020 20:44:57 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered 'Day 551' | System | 19 Nov 2020 20:44:57 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered '02 Mar 2022 00:01' | System | 19 Nov 2020 20:44:57 |

**US3802074**

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

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**Generated On: 10 Jun 2021 09:55:48**

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered '06 Mar 2022 23:59' | System | 19 Nov 2020 20:44:57 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered 'Day 558' | System | 19 Nov 2020 20:44:57 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered '09 Mar 2022 00:01' | System | 19 Nov 2020 20:44:57 |

**US3802074**

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

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered '13 Mar 2022 23:59' | System | 19 Nov 2020 20:44:57 |



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**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered 'Day 565' | System | 19 Nov 2020 20:44:57 |

**US3802074**

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

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**Generated On: 10 Jun 2021 09:55:48**

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered '16 Mar 2022 00:01' | System | 19 Nov 2020 20:44:57 |

**US3802074**

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

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered '20 Mar 2022 23:59' | System | 19 Nov 2020 20:44:57 |

**US3802074**

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**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered 'Day 572' | System | 19 Nov 2020 20:44:57 |

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

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered '23 Mar 2022 00:01' | System | 19 Nov 2020 20:44:57 |

**US3802074**

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

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered '27 Mar 2022 23:59' | System | 19 Nov 2020 20:44:57 |

**US3802074**

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**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered 'Day 579' | System | 19 Nov 2020 20:44:57 |

**US3802074**

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

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[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered '30 Mar 2022 00:01' | System | 19 Nov 2020 20:44:57 |



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

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered '03 Apr 2022 23:59' | System | 19 Nov 2020 20:44:57 |

**US3802074**

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

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**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered 'Day 586' | System | 19 Nov 2020 20:44:57 |

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered '06 Apr 2022 00:01' | System | 19 Nov 2020 20:44:57 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered '10 Apr 2022 23:59' | System | 19 Nov 2020 20:44:57 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered 'Day 593' | System | 19 Nov 2020 20:44:57 |

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered '13 Apr 2022 00:01' | System | 19 Nov 2020 20:44:57 |

**US3802074**

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

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**Generated On: 10 Jun 2021 09:55:48**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered '17 Apr 2022 23:59' | System | 19 Nov 2020 20:44:57 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered 'Day 600' | System | 19 Nov 2020 20:44:57 |



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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered '20 Apr 2022 00:01' | System | 19 Nov 2020 20:44:57 |

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

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered '24 Apr 2022 23:59' | System | 19 Nov 2020 20:44:57 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered 'Day 607' | System | 19 Nov 2020 20:44:57 |

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

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[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered '27 Apr 2022 00:01' | System | 19 Nov 2020 20:44:57 |

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

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered '01 May 2022 23:59' | System | 19 Nov 2020 20:44:57 |

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered 'Day 614' | System | 19 Nov 2020 20:44:57 |

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**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 | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered '04 May 2022 00:01' | System | 19 Nov 2020 20:44:57 |

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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 | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered '08 May 2022 23:59' | System | 19 Nov 2020 20:44:57 |



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**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered 'Day 621' | System | 19 Nov 2020 20:44:57 |

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

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered '11 May 2022 00:01' | System | 19 Nov 2020 20:44:57 |

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

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered '15 May 2022 23:59' | System | 19 Nov 2020 20:44:57 |

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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 | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered 'Day 628' | System | 19 Nov 2020 20:44:57 |

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

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered '18 May 2022 00:01' | System | 19 Nov 2020 20:44:57 |

**US3802074**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered '22 May 2022 23:59' | System | 19 Nov 2020 20:44:57 |

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered 'Day 635' | System | 19 Nov 2020 20:44:57 |

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered '25 May 2022 00:01' | System | 19 Nov 2020 20:44:57 |



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

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**Generated On: 10 Jun 2021 09:55:48**

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered '29 May 2022 23:59' | System | 19 Nov 2020 20:44:57 |

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered 'Day 642' | System | 19 Nov 2020 20:44:57 |

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

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered '01 Jun 2022 00:01' | System | 19 Nov 2020 20:44:57 |

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

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered '05 Jun 2022 23:59' | System | 19 Nov 2020 20:44:57 |

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

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**Generated On: 10 Jun 2021 09:55:48**

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| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered 'Day 649' | System | 19 Nov 2020 20:44:57 |

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**Folder: New Safety Follow Up Diary (1)**

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered '08 Jun 2022 00:01' | System | 19 Nov 2020 20:44:57 |

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**Folder: New Safety Follow Up Diary (1)**

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered '12 Jun 2022 23:59' | System | 19 Nov 2020 20:44:57 |

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered 'Day 656' | System | 19 Nov 2020 20:44:57 |



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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered '15 Jun 2022 00:01' | System | 19 Nov 2020 20:44:57 |

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**Folder: New Safety Follow Up Diary (1)**

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered '19 Jun 2022 23:59' | System | 19 Nov 2020 20:44:57 |

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**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 10 Jun 2021 09:55:48**

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| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered 'Day 663' | System | 19 Nov 2020 20:44:57 |

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**Folder: New Safety Follow Up Diary (1)**

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered '22 Jun 2022 00:01' | System | 19 Nov 2020 20:44:57 |

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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 | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered '26 Jun 2022 23:59' | System | 19 Nov 2020 20:44:57 |

**US3802074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered 'Day 670' | System | 19 Nov 2020 20:44:57 |

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered '29 Jun 2022 00:01' | System | 19 Nov 2020 20:44:57 |

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**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 10 Jun 2021 09:55:48**

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered '03 Jul 2022 23:59' | System | 19 Nov 2020 20:44:57 |



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered 'Day 677' | System | 19 Nov 2020 20:44:57 |

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**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 10 Jun 2021 09:55:48**

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered '06 Jul 2022 00:01' | System | 19 Nov 2020 20:44:57 |

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**Folder: New Safety Follow Up Diary (1)**

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered '10 Jul 2022 23:59' | System | 19 Nov 2020 20:44:57 |

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| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered 'Day 684' | System | 19 Nov 2020 20:44:57 |

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**Folder: New Safety Follow Up Diary (1)**

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered '13 Jul 2022 00:01' | System | 19 Nov 2020 20:44:57 |

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**Folder: New Safety Follow Up Diary (1)**

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered '17 Jul 2022 23:59' | System | 19 Nov 2020 20:44:57 |

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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 | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered 'Day 691' | System | 19 Nov 2020 20:44:57 |

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**Folder: New Safety Follow Up Diary (1)**

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered '20 Jul 2022 00:01' | System | 19 Nov 2020 20:44:57 |



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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered '24 Jul 2022 23:59' | System | 19 Nov 2020 20:44:57 |

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| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered 'Day 698' | System | 19 Nov 2020 20:44:57 |

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**Folder: New Safety Follow Up Diary (1)**

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered '27 Jul 2022 00:01' | System | 19 Nov 2020 20:44:57 |

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**Folder: New Safety Follow Up Diary (1)**

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered '31 Jul 2022 23:59' | System | 19 Nov 2020 20:44:57 |

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**Generated On: 10 Jun 2021 09:55:48**

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| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered 'Day 705' | System | 19 Nov 2020 20:44:57 |

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered '03 Aug 2022 00:01' | System | 19 Nov 2020 20:44:57 |

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**Folder: New Safety Follow Up Diary (1)**

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered '07 Aug 2022 23:59' | System | 19 Nov 2020 20:44:57 |

**US3802074**

**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 10 Jun 2021 09:55:48**

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| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered 'Day 712' | System | 19 Nov 2020 20:44:57 |



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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered '10 Aug 2022 00:01' | System | 19 Nov 2020 20:44:57 |

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered '14 Aug 2022 23:59' | System | 19 Nov 2020 20:44:57 |

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**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered 'Day 719' | System | 19 Nov 2020 20:44:57 |

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**Folder: New Safety Follow Up Diary (1)**

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered '17 Aug 2022 00:01' | System | 19 Nov 2020 20:44:57 |

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered '21 Aug 2022 23:59' | System | 19 Nov 2020 20:44:57 |

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**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered 'Day 726' | System | 19 Nov 2020 20:44:57 |

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**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 10 Jun 2021 09:55:48**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered '24 Aug 2022 00:01' | System | 19 Nov 2020 20:44:57 |

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**Folder: New Safety Follow Up Diary (1)**

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered '28 Aug 2022 23:59' | System | 19 Nov 2020 20:44:57 |



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**Generated On: 10 Jun 2021 09:55:48**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered 'Day 733' | System | 19 Nov 2020 20:44:57 |

**US3802074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered '31 Aug 2022 00:01' | System | 19 Nov 2020 20:44:57 |

**US3802074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered '04 Sep 2022 23:59' | System | 19 Nov 2020 20:44:57 |

**US3802074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered 'Day 740' | System | 19 Nov 2020 20:44:57 |

**US3802074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered '07 Sep 2022 00:01' | System | 19 Nov 2020 20:44:57 |

**US3802074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered '11 Sep 2022 23:59' | System | 19 Nov 2020 20:44:57 |

**US3802074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered 'Day 747' | System | 19 Nov 2020 20:44:57 |

**US3802074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered '14 Sep 2022 00:01' | System | 19 Nov 2020 20:44:57 |



**US3802074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered '18 Sep 2022 23:59' | System | 19 Nov 2020 20:44:57 |

**US3802074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered 'Day 754' | System | 19 Nov 2020 20:44:57 |

**US3802074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered '21 Sep 2022 00:01' | System | 19 Nov 2020 20:44:57 |

**US3802074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered '25 Sep 2022 23:59' | System | 19 Nov 2020 20:44:57 |

**US3802074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered 'Day 761' | System | 19 Nov 2020 20:44:57 |

**US3802074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered '28 Sep 2022 00:01' | System | 19 Nov 2020 20:44:57 |

**US3802074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered '02 Oct 2022 23:59' | System | 19 Nov 2020 20:44:57 |

**US3802074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered 'Day 768' | System | 19 Nov 2020 20:44:57 |



**US3802074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered '05 Oct 2022 00:01' | System | 19 Nov 2020 20:44:57 |

**US3802074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered '09 Oct 2022 23:59' | System | 19 Nov 2020 20:44:57 |

**US3802074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered 'Day 775' | System | 19 Nov 2020 20:44:57 |

**US3802074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered '12 Oct 2022 00:01' | System | 19 Nov 2020 20:44:57 |

**US3802074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered '16 Oct 2022 23:59' | System | 19 Nov 2020 20:44:57 |

**US3802074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered 'Day 782' | System | 19 Nov 2020 20:44:57 |

**US3802074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered '19 Oct 2022 00:01' | System | 19 Nov 2020 20:44:57 |

**US3802074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered '23 Oct 2022 23:59' | System | 19 Nov 2020 20:44:57 |



**US3802074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered 'Day 789' | System | 19 Nov 2020 20:44:57 |

**US3802074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered '26 Oct 2022 00:01' | System | 19 Nov 2020 20:44:57 |

**US3802074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered '30 Oct 2022 23:59' | System | 19 Nov 2020 20:44:57 |

**US3802074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered 'Day 796' | System | 19 Nov 2020 20:44:57 |

**US3802074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered '02 Nov 2022 00:01' | System | 19 Nov 2020 20:44:57 |

**US3802074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:48**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 20:44:57 |
| Amendment Manager: User entered '06 Nov 2022 23:59' | System | 19 Nov 2020 20:44:57 |

US3802074

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 10 Jun 2021 09:55:48**

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Apr 2021 18:07:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2021-03-07T12:20:14-05:00', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: 'edf418db-ef12-4065-b46f-6faba5f189df' | System           | 07 Mar 2021 17:20:23 |
| User entered 'No (N)'  | System           | 07 Mar 2021 17:20:23 |

**US3802074**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 10 Jun 2021 09:55:48**

[Date & Time of Submission](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Apr 2021 18:07:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3EC1C6D-56AF-47CB-B7F9-D4FAB5E37E72)', Time: '2021-03-07T12:20:20-05:00', User OID: 'PatientReportedOutcome (US3802074)', ODM File OID: 'edf418db-ef12-4065-b46f-6faba5f189df' User entered '07 Mar 2021 12:20:20' | System           | 07 Mar 2021 17:20:23 |
|  | System           | 07 Mar 2021 17:20:23 |



**US3802074**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:55:48**

[Was Contact Attempted?](#)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                | 29 Apr 2021 16:40:43 |
| User signature succeeded. | Judith Martin (b) (4)           | 28 Jan 2021 18:19:31 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)     | 04 Dec 2020 15:21:27 |
| User entered 'Yes (Y)'    | Emily Carney (b) (4)<br>(b) (4) | 23 Nov 2020 20:09:23 |

**US3802074**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:55:48**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

| Audit                      | User                            | Time (GMT)           |
|----------------------------|---------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                | 29 Apr 2021 16:40:43 |
| User signature succeeded.  | Judith Martin (b) (4)           | 28 Jan 2021 18:19:31 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6)     | 04 Dec 2020 15:21:27 |
| User entered '23 Nov 2020' | Emily Carney (b) (4)<br>(b) (4) | 23 Nov 2020 20:09:23 |

US3802074

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:55:48

[Please select one status for the follow-up contact](#)

| Audit                                      | User                            | Time (GMT)           |
|--|---------------------------------|----------------------|
| Data hard locked.                          | (b) (4), (b) (6)                | 29 Apr 2021 16:40:43 |
| User signature succeeded.                  | Judith Martin (b) (4)           | 28 Jan 2021 18:19:31 |
| DataPoint Verified.                        | (b) (4)<br>(b) (4), (b) (6)     | 04 Dec 2020 15:21:27 |
| User entered 'Contact Made (CONTACT MADE)' | Emily Carney (b) (4)<br>(b) (4) | 23 Nov 2020 20:09:23 |

US3802074

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:55:48

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                | 29 Apr 2021 16:40:43 |
| User signature succeeded. | Judith Martin (b) (4)           | 28 Jan 2021 18:19:31 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)     | 04 Dec 2020 15:21:27 |
| User entered empty.       | Emily Carney (b) (4)<br>(b) (4) | 23 Nov 2020 20:09:23 |

**US3802074**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:55:48**

[Is the participant continuing to the next visit?](#)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                | 29 Apr 2021 16:40:43 |
| User signature succeeded. | Judith Martin (b) (4)           | 28 Jan 2021 18:19:31 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)     | 04 Dec 2020 15:21:32 |
| User entered 'Yes (Y)'    | Emily Carney (b) (4)<br>(b) (4) | 23 Nov 2020 20:09:28 |

**US3802074**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:55:48**

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:40:43 |
| User entered 'I'  | System           | 23 Nov 2020 20:09:28 |

**US3802074**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:55:48**

[Was Contact Attempted?](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 27 Apr 2021 09:34:10 |
| DataPoint Verified.       |                       | 23 Apr 2021 14:03:12 |
| User signature succeeded. | Judith Martin (b) (4) | 28 Jan 2021 18:19:31 |
| User entered 'No (N)'     | (b) (4)               |                      |
|                           | Emily Carney (b) (4)  | 27 Jan 2021 18:25:51 |
|                           | (b) (4)               |                      |

**US3802074**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:55:48**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 27 Apr 2021 09:34:10 |
| DataPoint Verified.       |                       | 23 Apr 2021 14:03:12 |
| User signature succeeded. | Judith Martin (b) (4) | 28 Jan 2021 18:19:31 |
| User entered empty.       | (b) (4)               |                      |
|                           | Emily Carney (b) (4)  | 27 Jan 2021 18:25:51 |
|                           | (b) (4)               |                      |



**US3802074**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:55:48**

[Please select one status for the follow-up contact](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 27 Apr 2021 09:34:10 |
| DataPoint Verified.       |                       | 23 Apr 2021 14:03:12 |
| User signature succeeded. | Judith Martin (b) (4) | 28 Jan 2021 18:19:31 |
| User entered empty.       | (b) (4)               |                      |
|                           | Emily Carney (b) (4)  | 27 Jan 2021 18:25:51 |
|                           | (b) (4)               |                      |

US3802074

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:55:48

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 27 Apr 2021 09:34:10 |
| DataPoint Verified.       | (b) (4), (b) (6)      | 23 Apr 2021 14:03:12 |
| User signature succeeded. | Judith Martin (b) (4) | 28 Jan 2021 18:19:31 |
| User entered empty.       | Emily Carney (b) (4)  | 27 Jan 2021 18:25:51 |

**US3802074**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:55:48**

[Is the participant continuing to the next visit?](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 27 Apr 2021 09:34:10 |
| DataPoint Verified.       |                       | 19 Apr 2021 19:47:46 |
| User signature succeeded. | Judith Martin (b) (4) | 28 Jan 2021 18:19:31 |
| User entered 'Yes (Y)'    | (b) (4)               |                      |
|                           | Emily Carney (b) (4)  | 25 Jan 2021 15:59:00 |
|                           | (b) (4)               |                      |

**US3802074**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:55:48**

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 09:34:10 |
| User entered 'I'  | System           | 25 Jan 2021 15:59:00 |

**US3802074**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:55:48**

[Was Contact Attempted?](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 27 Apr 2021 09:34:10 |
| DataPoint Verified.       |                       | 11 Feb 2021 00:01:38 |
| User signature succeeded. | Judith Martin (b) (4) | 28 Jan 2021 18:19:31 |
| User entered 'Yes (Y)'    | (b) (4)               |                      |
|                           | Emily Carney (b) (4)  | 25 Jan 2021 15:59:12 |
|                           | (b) (4)               |                      |

US3802074

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:55:48

Date of Contact or Contact Attempt (*dd MMM yyyy*)

| Audit                      | User                                       | Time (GMT)           |
|----------------------------|--|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                           | 27 Apr 2021 09:34:10 |
| DataPoint Verified.        |  | 11 Feb 2021 00:01:38 |
| User signature succeeded.  | Judith Martin (b) (4)                      | 28 Jan 2021 18:19:31 |
| User entered '25 Jan 2021' | (b) (4)<br>Emily Carney (b) (4)<br>(b) (4) | 25 Jan 2021 15:59:12 |

**US3802074**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:55:48**

[Please select one status for the follow-up contact](#)

| Audit                                      | User                  | Time (GMT)           |
|--|-----------------------|----------------------|
| Data hard locked.                          | (b) (4), (b) (6)      | 27 Apr 2021 09:34:10 |
| DataPoint Verified.                        |                       | 11 Feb 2021 00:01:38 |
| User signature succeeded.                  | Judith Martin (b) (4) | 28 Jan 2021 18:19:31 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4)               |                      |
|  | Emily Carney (b) (4)  | 25 Jan 2021 15:59:12 |
|  | (b) (4)               |                      |

US3802074

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:55:48

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 27 Apr 2021 09:34:10 |
| DataPoint Verified.       |  | 11 Feb 2021 00:01:38 |
| User signature succeeded. | Judith Martin (b) (4)                      | 28 Jan 2021 18:19:31 |
| User entered empty.       | (b) (4)<br>Emily Carney (b) (4)<br>(b) (4) | 25 Jan 2021 15:59:12 |



US3802074

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:55:48

[Is the participant continuing to the next visit?](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 27 Apr 2021 09:34:10 |
| DataPoint Verified.       |                       | 11 Feb 2021 00:01:45 |
| User signature succeeded. | Judith Martin (b) (4) | 28 Jan 2021 18:19:31 |
| User entered 'Yes (Y)'    | (b) (4)               |                      |
|                           | Emily Carney (b) (4)  | 25 Jan 2021 15:59:18 |
|                           | (b) (4)               |                      |

**US3802074**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:55:48**

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 09:34:10 |
| User entered 'I'  | System           | 25 Jan 2021 15:59:18 |

**US3802074**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:55:48**

[Was Contact Attempted?](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 27 Apr 2021 09:34:10 |
| DataPoint Verified.       |                       | 23 Apr 2021 20:55:23 |
| User signature succeeded. | Judith Martin (b) (4) | 03 Mar 2021 16:29:49 |
| User entered 'Yes (Y)'    | (b) (4)               |                      |
|                           | Emily Carney (b) (4)  | 24 Feb 2021 19:23:45 |
|                           | (b) (4)               |                      |

**US3802074**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:55:48**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

| Audit                      | User                                       | Time (GMT)           |
|----------------------------|--|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                           | 27 Apr 2021 09:34:10 |
| DataPoint Verified.        |  | 23 Apr 2021 20:55:23 |
| User signature succeeded.  | Judith Martin (b) (4)                      | 03 Mar 2021 16:29:49 |
| User entered '24 Feb 2021' | (b) (4)<br>Emily Carney (b) (4)<br>(b) (4) | 24 Feb 2021 19:23:45 |

**US3802074**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:55:48**

[Please select one status for the follow-up contact](#)

| Audit                                      | User                                       | Time (GMT)           |
|--|--|----------------------|
| Data hard locked.                          | (b) (4), (b) (6)                           | 27 Apr 2021 09:34:10 |
| DataPoint Verified.                        |  | 23 Apr 2021 20:55:23 |
| User signature succeeded.                  | Judith Martin (b) (4)                      | 03 Mar 2021 16:29:49 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4)<br>Emily Carney (b) (4)<br>(b) (4) | 24 Feb 2021 19:23:45 |

US3802074

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:55:48

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 27 Apr 2021 09:34:10 |
| DataPoint Verified.       | (b) (4), (b) (6)      | 23 Apr 2021 20:55:23 |
| User signature succeeded. | Judith Martin (b) (4) | 03 Mar 2021 16:29:49 |
| User entered empty.       | Emily Carney (b) (4)  | 24 Feb 2021 19:23:45 |

US3802074

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:55:48

[Is the participant continuing to the next visit?](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 27 Apr 2021 09:34:10 |
| DataPoint Verified.       | (b) (4), (b) (6)      | 23 Apr 2021 14:03:29 |
| User signature succeeded. | Judith Martin (b) (4) | 03 Mar 2021 16:29:49 |
| User entered 'Yes (Y)'    | Emily Carney (b) (4)  | 24 Feb 2021 19:23:50 |

**US3802074**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:55:48**

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 09:34:10 |
| User entered 'I'  | System           | 24 Feb 2021 19:23:50 |



**US3802074**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:55:48**

[Was this visit performed?](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 27 Apr 2021 10:58:09 |
| DataPoint Verified.       |                       | 19 Apr 2021 20:11:21 |
| User signature succeeded. | Judith Martin (b) (4) | 25 Mar 2021 17:58:59 |
| User entered 'Yes (Y)'    | (b) (4)               |                      |
|                           | Lisa Vavro (b) (4)    | 25 Mar 2021 13:47:28 |
|                           | (b) (4)               |                      |

**US3802074**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:55:48**

[Visit date \(dd MMM yyyy\)](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 27 Apr 2021 10:58:09 |
| DataPoint Verified.        |                       | 19 Apr 2021 20:11:21 |
| User signature succeeded.  | Judith Martin (b) (4) | 25 Mar 2021 17:58:59 |
| User entered '25 Mar 2021' | (b) (4)               |                      |
|                            | Lisa Vavro (b) (4)    | 25 Mar 2021 13:47:28 |
|                            | (b) (4)               |                      |

US3802074

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:55:48

[Was visit performed at the participant's home or at the clinic?](#)

| Audit                          | User                                     | Time (GMT)           |
|--------------------------------|--|----------------------|
| Data hard locked.              | (b) (4), (b) (6)                         | 27 Apr 2021 10:58:09 |
| DataPoint Verified.            |  | 19 Apr 2021 20:11:21 |
| User signature succeeded.      | Judith Martin (b) (4)                    | 25 Mar 2021 17:58:59 |
| User entered 'Clinic (Clinic)' | (b) (4)<br>Lisa Vavro (b) (4)<br>(b) (4) | 25 Mar 2021 13:47:28 |

**US3802074**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:55:48**

[Folder OID](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| Data hard locked.     | (b) (4), (b) (6) | 27 Apr 2021 10:58:09 |
| User entered 'VISIT4' | System           | 25 Mar 2021 13:47:28 |

**US3802074**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:55:48**

[Were vital signs assessed?](#)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 27 Apr 2021 10:58:09 |
| DataPoint Verified.       | (b) (4), (b) (6)                           | 19 Apr 2021 20:02:35 |
| User signature succeeded. | Judith Martin (b) (4)                      | 31 Mar 2021 19:46:35 |
| User entered 'No (N)'     | (b) (4)<br>Emily Carney (b) (4)<br>(b) (4) | 31 Mar 2021 13:15:05 |

**US3802074**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:55:48**

[Date of assessment \(dd MMM yyyy\)](#)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 27 Apr 2021 10:58:09 |
| DataPoint Verified.       | (b) (4), (b) (6)                           | 19 Apr 2021 20:02:35 |
| User signature succeeded. | Judith Martin (b) (4)                      | 31 Mar 2021 19:46:35 |
| User entered empty.       | (b) (4)<br>Emily Carney (b) (4)<br>(b) (4) | 31 Mar 2021 13:15:05 |

**US3802074**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:55:48**

**Time of assessment (00:00-23:59)**

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 27 Apr 2021 10:58:09 |
| DataPoint Verified.       | (b) (4), (b) (6)                           | 19 Apr 2021 20:02:35 |
| User signature succeeded. | Judith Martin (b) (4)                      | 31 Mar 2021 19:46:35 |
| User entered empty.       | (b) (4)<br>Emily Carney (b) (4)<br>(b) (4) | 31 Mar 2021 13:15:05 |

**US3802074**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:55:48**

[Vital Signs Date and Time \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Apr 2021 10:58:09 |
| User entered empty. | System           | 31 Mar 2021 13:15:05 |



**US3802074**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:55:48**

[Temperature \(xxx.x\)](#)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 27 Apr 2021 10:58:09 |
| DataPoint Verified.       | (b) (4), (b) (6)                           | 19 Apr 2021 20:02:35 |
| User signature succeeded. | Judith Martin (b) (4)                      | 31 Mar 2021 19:46:35 |
| User entered empty.       | (b) (4)<br>Emily Carney (b) (4)<br>(b) (4) | 31 Mar 2021 13:15:05 |

**US3802074**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:55:48**

[Route of measurement](#)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 27 Apr 2021 10:58:09 |
| DataPoint Verified.       | (b) (4), (b) (6)                           | 19 Apr 2021 20:02:35 |
| User signature succeeded. | Judith Martin (b) (4)                      | 31 Mar 2021 19:46:35 |
| User entered empty.       | (b) (4)<br>Emily Carney (b) (4)<br>(b) (4) | 31 Mar 2021 13:15:05 |

**US3802074**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:55:48**

[If Other, specify](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 27 Apr 2021 10:58:09 |
| DataPoint Verified.       |                       | 19 Apr 2021 20:02:35 |
| User signature succeeded. | Judith Martin (b) (4) | 31 Mar 2021 19:46:35 |
| User entered empty.       | (b) (4)               |                      |
|                           | Emily Carney (b) (4)  | 31 Mar 2021 13:15:05 |
|                           | (b) (4)               |                      |

**US3802074**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:55:48**

[Pulse \(xxx\)](#)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 27 Apr 2021 10:58:09 |
| DataPoint Verified.       | (b) (4), (b) (6)                           | 19 Apr 2021 20:02:35 |
| User signature succeeded. | Judith Martin (b) (4)                      | 31 Mar 2021 19:46:35 |
| User entered empty.       | (b) (4)<br>Emily Carney (b) (4)<br>(b) (4) | 31 Mar 2021 13:15:05 |

**US3802074**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:55:48**

[Pulse units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Apr 2021 10:58:09 |
| User entered empty. | System           | 31 Mar 2021 13:15:05 |

US3802074

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:55:48

[Respiratory Rate \(xxx\)](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 27 Apr 2021 10:58:09 |
| DataPoint Verified.       |                       | 19 Apr 2021 20:02:35 |
| User signature succeeded. | Judith Martin (b) (4) | 31 Mar 2021 19:46:35 |
| User entered empty.       | (b) (4)               |                      |
|                           | Emily Carney (b) (4)  | 31 Mar 2021 13:15:05 |
|                           | (b) (4)               |                      |

**US3802074**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:55:48**

[Respiratory Rate units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Apr 2021 10:58:09 |
| User entered empty. | System           | 31 Mar 2021 13:15:05 |

**US3802074**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:55:48**

[Systolic Blood Pressure \(xxx\)](#)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 27 Apr 2021 10:58:09 |
| DataPoint Verified.       | (b) (4), (b) (6)                           | 19 Apr 2021 20:02:35 |
| User signature succeeded. | Judith Martin (b) (4)                      | 31 Mar 2021 19:46:35 |
| User entered empty.       | (b) (4)<br>Emily Carney (b) (4)<br>(b) (4) | 31 Mar 2021 13:15:05 |



**US3802074**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:55:48**

[Systolic Blood Pressure units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Apr 2021 10:58:09 |
| User entered empty. | System           | 31 Mar 2021 13:15:05 |

US3802074

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:55:48

Diastolic Blood Pressure (xxx)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 27 Apr 2021 10:58:09 |
| DataPoint Verified.       |                       | 19 Apr 2021 20:02:35 |
| User signature succeeded. | Judith Martin (b) (4) | 31 Mar 2021 19:46:35 |
| User entered empty.       | (b) (4)               |                      |
|                           | Emily Carney (b) (4)  | 31 Mar 2021 13:15:05 |
|                           | (b) (4)               |                      |

**US3802074**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:55:48**

[Diastolic Blood Pressure units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Apr 2021 10:58:09 |
| User entered empty. | System           | 31 Mar 2021 13:15:05 |

**US3802074**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:55:48**

[Height \(derived\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 10:58:09 |
|                   |                  |                      |

**US3802074**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:55:48**

[Weight \(derived\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 10:58:09 |
|                   |                  |                      |

**US3802074**

**Folder: Visit 4 Day 209 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:55:48**

[Was the physical examination performed?](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 27 Apr 2021 10:58:09 |
| DataPoint Verified.       |                       | 19 Apr 2021 20:02:55 |
| User signature succeeded. | Judith Martin (b) (4) | 25 Mar 2021 17:58:59 |
|                           | (b) (4)               |                      |
| User entered 'No (N)'     | Lisa Vavro (b) (4)    | 25 Mar 2021 13:47:35 |
|                           | (b) (4)               |                      |

**US3802074**

**Folder: Visit 4 Day 209 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:55:48**

**Date of examination (dd MMM yyyy)**

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 27 Apr 2021 10:58:09 |
| DataPoint Verified.       |                       | 19 Apr 2021 20:02:55 |
| User signature succeeded. | Judith Martin (b) (4) | 25 Mar 2021 17:58:59 |
| User entered empty.       | (b) (4)               |                      |
|                           | Lisa Vavro (b) (4)    | 25 Mar 2021 13:47:35 |
|                           | (b) (4)               |                      |

**US3802074**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:55:48**

[Was the sample collected?](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 27 Apr 2021 10:58:09 |
| DataPoint Verified.       |                       | 19 Apr 2021 19:46:29 |
| User signature succeeded. | Judith Martin (b) (4) | 25 Mar 2021 17:58:59 |
| User entered 'Yes (Y)'    | (b) (4)               |                      |
|                           | Lisa Vavro (b) (4)    | 25 Mar 2021 13:47:58 |
|                           | (b) (4)               |                      |



**US3802074**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:55:48**

**Collection date** (*dd MMM yyyy*)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 27 Apr 2021 10:58:09 |
| DataPoint Verified.        |                       | 19 Apr 2021 19:46:29 |
| User signature succeeded.  | Judith Martin (b) (4) | 25 Mar 2021 17:58:59 |
| User entered '25 Mar 2021' | (b) (4)               |                      |
|                            | Lisa Vavro (b) (4)    | 25 Mar 2021 13:47:58 |
|                            | (b) (4)               |                      |

**US3802074**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:55:48**

[Collection time \(00:00-23:59\)](#)

| Audit                     | User                                     | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                         | 27 Apr 2021 10:58:09 |
| DataPoint Verified.       | (b) (4), (b) (6)                         | 19 Apr 2021 19:46:29 |
| User signature succeeded. | Judith Martin (b) (4)                    | 25 Mar 2021 17:58:59 |
| User entered '09:25'      | (b) (4)<br>Lisa Vavro (b) (4)<br>(b) (4) | 25 Mar 2021 13:47:58 |

**US3802074**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:55:48**

[Collection date and time \(derived\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 27 Apr 2021 10:58:09 |
| User entered '25 Mar 2021 09:25' | System           | 25 Mar 2021 13:47:58 |

**US3802074**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:55:48**

[Is the participant continuing to the next visit?](#)

| Audit                     | User                                     | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                         | 27 Apr 2021 10:58:09 |
| DataPoint Verified.       | (b) (4), (b) (6)                         | 19 Apr 2021 19:13:22 |
| User signature succeeded. | Judith Martin (b) (4)                    | 25 Mar 2021 17:58:59 |
| User entered 'Yes (Y)'    | (b) (4)<br>Lisa Vavro (b) (4)<br>(b) (4) | 25 Mar 2021 13:48:05 |

**US3802074**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:55:48**

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 10:58:09 |
| User entered 'I'  | System           | 25 Mar 2021 13:48:05 |

**US3802074**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:55:48**

[Was Contact Attempted?](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4) | 26 Apr 2021 19:01:59 |
| User entered 'Yes (Y)'    | Emily Carney (b) (4)  | 26 Apr 2021 14:33:52 |

**US3802074**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:55:48**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| User signature succeeded.  | Judith Martin (b) (4) | 26 Apr 2021 19:01:59 |
|                            | (b) (4)               |                      |
| User entered '26 Apr 2021' | Emily Carney (b) (4)  | 26 Apr 2021 14:33:52 |
|                            | (b) (4)               |                      |

**US3802074**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:55:48**

[Please select one status for the follow-up contact](#)

| Audit                                      | User                                       | Time (GMT)           |
|--|--|----------------------|
| User signature succeeded.                  | Judith Martin (b) (4)                      | 26 Apr 2021 19:01:59 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4)<br>Emily Carney (b) (4)<br>(b) (4) | 26 Apr 2021 14:33:52 |



**US3802074**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:55:48**

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4)           | 26 Apr 2021 19:01:59 |
| User entered empty.       | (b) (4)<br>Emily Carney (b) (4) | 26 Apr 2021 14:33:52 |

**US3802074**

**Folder: Safety Call Day 239 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:55:48**

[Is the participant continuing to the next visit?](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4) | 26 Apr 2021 19:01:59 |
| User entered 'Yes (Y)'    | Emily Carney (b) (4)  | 26 Apr 2021 14:33:57 |

**US3802074**

**Folder: Safety Call Day 239 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:55:48**

[Continuing Flag](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered 'I' | System | 26 Apr 2021 14:33:57 |

US3802074

Folder: Covid-19 Assessment 06 Jan 2021

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:55:48

[Date of Contact](#)

| Audit   | User                     | Time (GMT)           |                      |
|---|--------------------------|----------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)         | 03 May 2021 19:59:41 |                      |
| User signature succeeded.   | Judith Martin (b) (4)    | 30 Apr 2021 16:16:20 |                      |
| User closed query 'Data is required. Please complete.' (Site from System).                | (b) (4)                  | (b) (4), (b) (6)     | 29 Apr 2021 18:51:41 |
| DataPoint Verified.   |                          |                      | 23 Apr 2021 18:04:20 |
| Query 'Data is required. Please complete.' answered with 'data error' (Site from System). | Emily Dougherty (b) (4)  | (b) (4)              | 23 Apr 2021 17:20:23 |
| User opened query 'Data is required. Please complete.' (Site from System).                | System                   |                      | 23 Apr 2021 17:20:16 |
| Signature has been broken.  | Emily Dougherty (b) (4)  | (b) (4)              | 23 Apr 2021 17:20:16 |
| User entered empty; reason for change Data Entry Error                                    | Emily Dougherty (b) (4)  | (b) (4)              | 23 Apr 2021 17:20:16 |
| User signature succeeded.   | Judith Martin (b) (4)    | (b) (4)              | 28 Jan 2021 18:19:31 |
| User entered '06 Jan 2021'  | Melissa Andrasko (b) (4) | (b) (4)              | 22 Jan 2021 19:13:46 |

US3802074

Folder: Covid-19 Assessment 06 Jan 2021

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:55:48

[Time of Contact](#)

| Audit   | User                     | Time (GMT)           |
|---|--------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)         | 03 May 2021 19:59:41 |
| User signature succeeded.   | Judith Martin (b) (4)    | 30 Apr 2021 16:16:20 |
| User closed query 'Data is required. Please complete.' (Site from System).                | (b) (4)                  | 29 Apr 2021 18:51:39 |
| DataPoint Verified.   | (b) (4), (b) (6)         | 23 Apr 2021 18:04:22 |
| Query 'Data is required. Please complete.' answered with 'data error' (Site from System). | Emily Dougherty (b) (4)  | 23 Apr 2021 17:20:29 |
| User opened query 'Data is required. Please complete.' (Site from System).                | (b) (4)                  |                      |
| Signature has been broken.  | System                   | 23 Apr 2021 17:20:16 |
| User entered empty; reason for change Data Entry Error                                    | Emily Dougherty (b) (4)  | 23 Apr 2021 17:20:16 |
| User signature succeeded.   | Emily Dougherty (b) (4)  | 23 Apr 2021 17:20:16 |
| User entered '20:00'  | Judith Martin (b) (4)    | 28 Jan 2021 18:19:31 |
|   | (b) (4)                  |                      |
|   | Melissa Andrasko (b) (4) | 22 Jan 2021 19:13:46 |
|   |                          |                      |
|   |                          |                      |

**US3802074**

**Folder: Covid-19 Assessment 06 Jan 2021**

**Form: COVID-19 Contact**

**Generated On: 10 Jun 2021 09:55:48**

[Date and Time of Contact \(derived\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 03 May 2021 19:59:41 |
| User entered empty.              | System           | 23 Apr 2021 17:20:16 |
| User entered '06 Jan 2021 20:00' | System           | 22 Jan 2021 19:13:46 |

US3802074

Folder: Covid-19 Assessment 06 Jan 2021

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:55:48

[Type of Contact](#)

| Audit   | User                     | Time (GMT)           |
|---|--------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)         | 03 May 2021 19:59:41 |
| User signature succeeded.   | Judith Martin (b) (4)    | 30 Apr 2021 16:16:20 |
| User closed query 'Data is required. Please complete.' (Site from System).                | (b) (4)                  | 29 Apr 2021 18:51:42 |
| DataPoint Verified.   | (b) (4), (b) (6)         | 23 Apr 2021 18:04:24 |
| Query 'Data is required. Please complete.' answered with 'data error' (Site from System). | Emily Dougherty (b) (4)  | 23 Apr 2021 17:20:34 |
| User opened query 'Data is required. Please complete.' (Site from System).                | (b) (4)                  |                      |
| Signature has been broken.  | System                   | 23 Apr 2021 17:20:16 |
| User entered empty; reason for change Data Entry Error                                    | Emily Dougherty (b) (4)  | 23 Apr 2021 17:20:16 |
| User signature succeeded.   | Emily Dougherty (b) (4)  | 23 Apr 2021 17:20:16 |
| User entered 'Safety Call (Safety Call)'  | Judith Martin (b) (4)    | 28 Jan 2021 18:19:31 |
|   | (b) (4)                  |                      |
|   | Melissa Andrasko (b) (4) | 22 Jan 2021 19:13:46 |
|   |                          |                      |
|   |                          |                      |

US3802074

Folder: Covid-19 Assessment 06 Jan 2021

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:55:48

[Has the subject reported symptoms of SARS-COV-2?](#)

| Audit   | User                     | Time (GMT)           |
|---|--------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)         | 03 May 2021 19:59:41 |
| User signature succeeded.   | Judith Martin (b) (4)    | 30 Apr 2021 16:16:20 |
| User closed query 'Data is required. Please complete.' (Site from System).                | (b) (4)                  | 29 Apr 2021 18:51:44 |
| DataPoint Verified.   | (b) (4), (b) (6)         | 23 Apr 2021 18:04:27 |
| Query 'Data is required. Please complete.' answered with 'data error' (Site from System). | Emily Dougherty (b) (4)  | 23 Apr 2021 17:20:39 |
| User opened query 'Data is required. Please complete.' (Site from System).                | (b) (4)                  | 23 Apr 2021 17:20:16 |
| Signature has been broken.  | System                   | 23 Apr 2021 17:20:16 |
| User entered empty; reason for change Data Entry Error                                    | Emily Dougherty (b) (4)  | 23 Apr 2021 17:20:16 |
| User signature succeeded.   | Emily Dougherty (b) (4)  | 23 Apr 2021 17:20:16 |
| User entered 'No (N)'   | Judith Martin (b) (4)    | 28 Jan 2021 18:19:31 |
|   | (b) (4)                  |                      |
|   | Melissa Andrasko (b) (4) | 22 Jan 2021 19:13:46 |
|   |                          |                      |
|   |                          |                      |



US3802074

Folder: Covid-19 Assessment 06 Jan 2021

Form: Generate Next COVID-19 Assessment

Generated On: 10 Jun 2021 09:55:48

[Generate Next COVID-19 Assessment](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 03 May 2021 19:59:47 |
| DataPoint Verified.       |                       | 23 Apr 2021 14:00:17 |
| User signature succeeded. | Judith Martin (b) (4) | 28 Jan 2021 18:19:31 |
| User entered 'No (N)'     | (b) (4)               |                      |
|                           | Emily Carney (b) (4)  | 28 Jan 2021 14:21:24 |
|                           | (b) (4)               |                      |

**US3802074**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:55:48**

[Was this visit performed?](#)

| Audit                     | User   | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                             | 30 Apr 2021 11:26:43 |
| DataPoint Verified.       |  | 14 Apr 2021 13:39:32 |
| User signature succeeded. | Judith Martin (b) (4)                        | 28 Jan 2021 18:19:31 |
| User entered 'Yes (Y)'    | (b) (4)<br>Dominic Kramer (b) (4)<br>(b) (4) | 13 Jan 2021 14:12:14 |

**US3802074**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:55:48**

[Visit date \(dd MMM yyyy\)](#)

| Audit                      | User   | Time (GMT)           |
|----------------------------|--|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                             | 30 Apr 2021 11:26:43 |
| DataPoint Verified.        |  | 14 Apr 2021 13:39:32 |
| User signature succeeded.  | Judith Martin (b) (4)                        | 28 Jan 2021 18:19:31 |
| User entered '13 Jan 2021' | (b) (4)<br>Dominic Kramer (b) (4)<br>(b) (4) | 13 Jan 2021 14:12:14 |

**US3802074**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:55:48**

[Was visit performed at the participant's home or at the clinic?](#)

| Audit                          | User   | Time (GMT)           |
|--------------------------------|--|----------------------|
| Data hard locked.              | (b) (4), (b) (6)                             | 30 Apr 2021 11:26:43 |
| DataPoint Verified.            |  | 14 Apr 2021 13:39:32 |
| User signature succeeded.      | Judith Martin (b) (4)                        | 28 Jan 2021 18:19:31 |
| User entered 'Clinic (Clinic)' | (b) (4)<br>Dominic Kramer (b) (4)<br>(b) (4) | 13 Jan 2021 14:12:14 |

**US3802074**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:55:48**

[Folder OID](#)

| Audit                        | User             | Time (GMT)           |
|------------------------------|------------------|----------------------|
| Data hard locked.            | (b) (4), (b) (6) | 30 Apr 2021 11:26:43 |
| User entered 'UNBLND_DECIDE' | System           | 13 Jan 2021 14:12:14 |

**US3802074**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:55:48**

[Date of updated informed consent \(dd MMM yyyy\)](#)

| Audit                      | User   | Time (GMT)           |
|----------------------------|--|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                             | 30 Apr 2021 11:26:43 |
| DataPoint Verified.        |  | 14 Apr 2021 13:41:00 |
| User signature succeeded.  | Judith Martin (b) (4)                        | 28 Jan 2021 18:19:31 |
| User entered '13 Jan 2021' | (b) (4)<br>Dominic Kramer (b) (4)<br>(b) (4) | 13 Jan 2021 14:12:39 |

**US3802074**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:55:48**

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

| Audit                                      | User                            | Time (GMT)           |
|--|---------------------------------|----------------------|
| Data hard locked.                          | (b) (4), (b) (6)                | 30 Apr 2021 11:26:43 |
| DataPoint Verified.                        |                                 | 14 Apr 2021 13:41:00 |
| User signature succeeded.                  | Judith Martin (b) (4)           | 08 Apr 2021 18:35:41 |
| User entered '0'                           | (b) (4)<br>Emily Carney (b) (4) | 08 Apr 2021 15:19:50 |
| Amendment Manager inserted this DataPoint. | (b) (4)<br>System               | 06 Mar 2021 18:01:31 |

**US3802074**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:55:48**

[Was the participant unblinded?](#)

| Audit                     | User   | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                             | 30 Apr 2021 11:26:43 |
| DataPoint Verified.       |  | 14 Apr 2021 13:41:00 |
| User signature succeeded. | Judith Martin (b) (4)                        | 28 Jan 2021 18:19:31 |
| User entered 'Yes (Y)'    | (b) (4)<br>Dominic Kramer (b) (4)<br>(b) (4) | 13 Jan 2021 14:12:39 |



US3802074

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:55:48

[Under what version of the Protocol was the Participant unblinded?](#)

| Audit   | User                             | Time (GMT)           |
|---|----------------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)                 | 30 Apr 2021 11:26:43 |
| User closed query 'Per CDM, per Sponsor Review: IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field. ' (Site from DM).<br>DataPoint Verified. |                                  | 16 Apr 2021 01:23:50 |
|   |                                  | 14 Apr 2021 13:41:00 |
| User signature succeeded.   | Judith Martin (b) (4)<br>(b) (4) | 08 Apr 2021 18:35:41 |
| Query 'Per CDM, per Sponsor Review: IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field. ' answered with 'updated' (Site from DM).            | Emily Carney (b) (4)<br>(b) (4)  | 08 Apr 2021 15:20:18 |
| User entered 'Amendment 6 or later (Amendment 6 or later)'  | Emily Carney (b) (4)<br>(b) (4)  | 08 Apr 2021 15:19:50 |
| User opened query 'Per CDM, per Sponsor Review: IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field. ' (Site from DM).                        | (b) (4), (b) (6)                 | 08 Apr 2021 10:39:44 |
| Amendment Manager inserted this DataPoint.  | System                           | 06 Mar 2021 18:01:31 |

US3802074

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:55:48

Date of unblinding (*dd MMM yyyy*)

| Audit                      | User   | Time (GMT)           |
|----------------------------|--|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                             | 30 Apr 2021 11:26:43 |
| DataPoint Verified.        |  | 14 Apr 2021 13:41:00 |
| User signature succeeded.  | Judith Martin (b) (4)                        | 28 Jan 2021 18:19:31 |
| User entered '13 Jan 2021' | (b) (4)<br>Dominic Kramer (b) (4)<br>(b) (4) | 13 Jan 2021 14:12:39 |

US3802074

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:55:48

[Participant randomization assignment](#)

| Audit                                | User   | Time (GMT)           |
|--------------------------------------|--|----------------------|
| Data hard locked.                    | (b) (4), (b) (6)                             | 30 Apr 2021 11:26:43 |
| DataPoint Verified.                  |  | 14 Apr 2021 13:41:00 |
| User signature succeeded.            | Judith Martin (b) (4)                        | 28 Jan 2021 18:19:31 |
| User entered 'mRNA-1273 (mRNA-1273)' | (b) (4)<br>Dominic Kramer (b) (4)<br>(b) (4) | 13 Jan 2021 14:12:39 |

**US3802074**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:55:48**

[Actual Dose 1](#)

| Audit   | User                   | Time (GMT)           |
|---|------------------------|----------------------|
| Data hard locked.                                       | (b) (4), (b) (6)       | 30 Apr 2021 11:26:43 |
| DataPoint Verified.                                     |                        | 14 Apr 2021 13:41:00 |
| User signature succeeded.                               | Judith Martin (b) (4)  | 28 Jan 2021 18:19:31 |
| Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)' | (b) (4)                |                      |
|   | System                 | 20 Jan 2021 13:25:43 |
| User entered 'mRNA-1273 (mRNA-1273)'                    | Dominic Kramer (b) (4) | 13 Jan 2021 14:12:39 |
|   | (b) (4)                |                      |

**US3802074**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:55:48**

[Actual Dose 2](#)

| Audit   | User                   | Time (GMT)           |
|---|------------------------|----------------------|
| Data hard locked.                                       | (b) (4), (b) (6)       | 30 Apr 2021 11:26:43 |
| DataPoint Verified.                                     |                        | 14 Apr 2021 13:41:00 |
| User signature succeeded.                               | Judith Martin (b) (4)  | 28 Jan 2021 18:19:31 |
| Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)' | (b) (4)                |                      |
|   | System                 | 20 Jan 2021 13:25:43 |
| User entered 'mRNA-1273 (mRNA-1273)'                    | Dominic Kramer (b) (4) | 13 Jan 2021 14:12:39 |
|   | (b) (4)                |                      |

US3802074

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:55:48

[Will participant receive mRNA-1273?](#)

| Audit                     | User   | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                             | 30 Apr 2021 11:26:43 |
| DataPoint Verified.       |  | 14 Apr 2021 13:41:00 |
| User signature succeeded. | Judith Martin (b) (4)                        | 28 Jan 2021 18:19:31 |
| User entered 'No (N)'     | (b) (4)<br>Dominic Kramer (b) (4)<br>(b) (4) | 13 Jan 2021 14:12:39 |

**US3802074**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:55:48**

[Placebo Only Flag](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 30 Apr 2021 11:26:43 |
| User entered empty. | System           | 13 Jan 2021 14:12:39 |

**US3802074**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:55:48**

[Continuing with mRNA-1273](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 30 Apr 2021 11:26:43 |
| User entered empty. | System           | 13 Jan 2021 14:12:39 |



US3802074

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:55:48

[Was the sample collected?](#)

| Audit                     | User   | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                             | 30 Apr 2021 11:26:43 |
| DataPoint Verified.       |  | 14 Apr 2021 13:42:22 |
| User signature succeeded. | Judith Martin (b) (4)                        | 28 Jan 2021 18:19:31 |
| User entered 'Yes (Y)'    | (b) (4)<br>Dominic Kramer (b) (4)<br>(b) (4) | 13 Jan 2021 14:12:54 |

**US3802074**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:55:48**

**Collection date** (*dd MMM yyyy*)

| Audit                      | User   | Time (GMT)           |
|----------------------------|--|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                             | 30 Apr 2021 11:26:43 |
| DataPoint Verified.        |  | 14 Apr 2021 13:42:22 |
| User signature succeeded.  | Judith Martin (b) (4)                        | 28 Jan 2021 18:19:31 |
| User entered '13 Jan 2021' | (b) (4)<br>Dominic Kramer (b) (4)<br>(b) (4) | 13 Jan 2021 14:12:54 |

**US3802074**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:55:48**

[Collection time \(00:00-23:59\)](#)

| Audit                     | User   | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                             | 30 Apr 2021 11:26:43 |
| DataPoint Verified.       |  | 14 Apr 2021 13:42:22 |
| User signature succeeded. | Judith Martin (b) (4)                        | 28 Jan 2021 18:19:31 |
| User entered '08:40'      | (b) (4)<br>Dominic Kramer (b) (4)<br>(b) (4) | 13 Jan 2021 14:12:54 |

**US3802074**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:55:48**

[Collection date and time \(derived\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 30 Apr 2021 11:26:43 |
| User entered '13 Jan 2021 08:40' | System           | 13 Jan 2021 14:12:54 |

**US3802074**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 10 Jun 2021 09:55:48**

[Was the sample collected?](#)

| Audit                     | User   | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                             | 30 Apr 2021 11:26:43 |
| DataPoint Verified.       |  | 14 Apr 2021 13:41:59 |
| User signature succeeded. | Judith Martin (b) (4)                        | 28 Jan 2021 18:19:31 |
| User entered 'Yes (Y)'    | (b) (4)<br>Dominic Kramer (b) (4)<br>(b) (4) | 13 Jan 2021 14:13:06 |

**US3802074**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 10 Jun 2021 09:55:48**

[Collection date \(dd MMM yyyy\)](#)

| Audit                      | User   | Time (GMT)           |
|----------------------------|--|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                             | 30 Apr 2021 11:26:43 |
| DataPoint Verified.        |  | 14 Apr 2021 13:41:59 |
| User signature succeeded.  | Judith Martin (b) (4)                        | 28 Jan 2021 18:19:31 |
| User entered '13 Jan 2021' | (b) (4)<br>Dominic Kramer (b) (4)<br>(b) (4) | 13 Jan 2021 14:13:06 |

**US3802074**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 10 Jun 2021 09:55:48**

[Collection time \(00:00 - 23:59\)](#)

| Audit                     | User   | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                             | 30 Apr 2021 11:26:43 |
| DataPoint Verified.       |  | 14 Apr 2021 13:41:59 |
| User signature succeeded. | Judith Martin (b) (4)                        | 28 Jan 2021 18:19:31 |
| User entered '08:35'      | (b) (4)<br>Dominic Kramer (b) (4)<br>(b) (4) | 13 Jan 2021 14:13:06 |

**US3802074**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 10 Jun 2021 09:55:48**

[Collection Date and Time \(derived\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 30 Apr 2021 11:26:43 |
| User entered '13 Jan 2021 08:35' | System           | 13 Jan 2021 14:13:06 |



US3802074

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 09:55:48

[Did the participant experience any adverse events?](#)

| Audit  | User                             | Time (GMT)           |
|--|----------------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)                 | 03 May 2021 05:57:44 |
| DataPoint Verified.  |                                  | 15 Apr 2021 14:02:12 |
| User signature succeeded.                                  | Judith Martin (b) (4)            | 31 Mar 2021 19:46:35 |
| Signature has been broken.                                 | (b) (4)<br>Lisa Vavro (b) (4)    | 31 Mar 2021 15:29:15 |
| User entered 'Yes (Y)' reason for change: Data Entry Error | (b) (4)<br>Lisa Vavro (b) (4)    | 31 Mar 2021 15:29:15 |
| User signature succeeded.                                  | (b) (4)<br>Judith Martin (b) (4) | 13 Feb 2021 12:27:55 |
| User entered 'No (N)'                                      | (b) (4)<br>Jennifer Nagg (b) (4) | 05 Feb 2021 19:03:36 |
|  | (b) (4)                          |                      |

**US3802074**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:55:48**

[AEID](#)

| Audit                                 | User                  | Time (GMT)           |
|---------------------------------------|-----------------------|----------------------|
| DataPoint Verified.                   | (b) (4), (b) (6)      | 15 Apr 2021 14:07:26 |
| Reviewed for Safety.                  |                       | 06 Apr 2021 12:40:49 |
| User signature succeeded.             | Judith Martin (b) (4) | 01 Apr 2021 19:12:08 |
| User entered                          | (b) (4)               |                      |
| 'USA-US098-2021-mRNA-1273-P301000003' | System                | 01 Apr 2021 15:47:22 |
| User entered 'New'                    | (b) (4), (b) (6)      | 01 Apr 2021 15:47:22 |
|                                       |                       |                      |

US3802074

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:55:48

[Adverse event](#)

| Audit   | User                     | Time (GMT)           |
|---|--------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)         | 15 Apr 2021 14:07:28 |
| User signature succeeded.   | Judith Martin (b) (4)    | 01 Apr 2021 19:12:08 |
| User coded data point as SOC: Hepatobiliary disorders, HLG: Gallbladder disorders, HLT: Cholecystitis and cholelithiasis, PT: Cholecystitis acute, LLT: Acute cholecystitis - version MedDRA\23.0.                                    | Coder Import (b) (4)     | 01 Apr 2021 15:25:37 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.   | Coder Import (b) (4)     | 01 Apr 2021 15:25:37 |
| Data point term sent to Coder   | System                   | 01 Apr 2021 15:24:55 |
| Coding entries removed.   | Melissa Andrasko (b) (4) | 01 Apr 2021 15:24:18 |
| Signature has been broken.  | Melissa Andrasko (b) (4) | 01 Apr 2021 15:24:18 |
| User entered 'Acute CHOLECYstitis' reason for change: Data Entry Error  | Melissa Andrasko (b) (4) | 01 Apr 2021 15:24:18 |
| User signature succeeded.   | Judith Martin (b) (4)    | 31 Mar 2021 19:46:35 |
| User coded data point as SOC: Surgical and medical procedures, HLG: Hepatobiliary therapeutic procedures, HLT: Biliary tract and gallbladder therapeutic procedures, PT: Cholecystectomy, LLT: Cholecystectomy - version MedDRA\23.0. | Coder Import (b) (4)     | 31 Mar 2021 15:37:11 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.   | Coder Import (b) (4)     | 31 Mar 2021 15:37:11 |
| Data point term sent to Coder   | System                   | 31 Mar 2021 15:35:05 |
| User entered 'Cholecystectomy'  | Lisa Vavro (b) (4)       | 31 Mar 2021 15:34:14 |

**US3802074**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:55:48**

[Was this a medically-attended AE?](#)

| Audit                     | User                                     | Time (GMT)           |
|---------------------------|--|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)                         | 15 Apr 2021 14:07:30 |
| User signature succeeded. | Judith Martin (b) (4)                    | 31 Mar 2021 19:46:35 |
| User entered 'Yes (Y)'    | (b) (4)<br>Lisa Vavro (b) (4)<br>(b) (4) | 31 Mar 2021 15:34:14 |

US3802074

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:55:48

[Was this a Solicited Adverse Reaction?](#)

| Audit   | User                     | Time (GMT)           |
|---|--------------------------|----------------------|
| DataPoint Verified.                                       | (b) (4), (b) (6)         | 15 Apr 2021 14:07:32 |
| User signature succeeded.                                 | Judith Martin (b) (4)    | 01 Apr 2021 19:12:08 |
| Signature has been broken.                                | (b) (4)                  |                      |
|   | Melissa Andrasko (b) (4) | 01 Apr 2021 15:24:18 |
|   |                          |                      |
| User entered 'No (N)' reason for change: Data Entry Error | Melissa Andrasko (b) (4) | 01 Apr 2021 15:24:18 |
|   |                          |                      |
| User signature succeeded.                                 | Judith Martin (b) (4)    | 31 Mar 2021 19:46:35 |
|   | (b) (4)                  |                      |
| User entered 'Yes (Y)'                                    | Lisa Vavro (b) (4)       | 31 Mar 2021 15:34:14 |
|   | (b) (4)                  |                      |

US3802074

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:55:48

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit                     | User                                     | Time (GMT)           |
|---------------------------|--|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)                         | 15 Apr 2021 14:07:34 |
| User signature succeeded. | Judith Martin (b) (4)                    | 31 Mar 2021 19:46:35 |
| User entered 'No (N)'     | (b) (4)<br>Lisa Vavro (b) (4)<br>(b) (4) | 31 Mar 2021 15:34:14 |

US3802074

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:55:48

Start date (dd MMM yyyy)

| Audit  | User                          | Time (GMT)           |
|--|-------------------------------|----------------------|
| DataPoint Verified.  | (b) (4), (b) (6)              | 15 Apr 2021 14:07:36 |
| User signature succeeded.  | Judith Martin (b) (4)         | 08 Apr 2021 18:35:41 |
| User closed query 'PV Query: EDC shows event start date as 26 Mar 2021 but SAE paper form shows 27 Mar 2021. Please confirm correct date in EDC accordingly. ' (Site from Safety).               | (b) (4)<br>(b) (4), (b) (6)   | 08 Apr 2021 16:40:43 |
| Query 'PV Query: EDC shows event start date as 26 Mar 2021 but SAE paper form shows 27 Mar 2021. Please confirm correct date in EDC accordingly. ' answered with 'corrected' (Site from Safety). | Melissa Andrasko (b) (4)      | 07 Apr 2021 20:12:27 |
| Signature has been broken.   | Melissa Andrasko (b) (4)      | 07 Apr 2021 20:12:01 |
| User entered '27 Mar 2021' reason for change: Data Entry Error   | Melissa Andrasko (b) (4)      | 07 Apr 2021 20:12:01 |
| User opened query 'PV Query: EDC shows event start date as 26 Mar 2021 but SAE paper form shows 27 Mar 2021. Please confirm correct date in EDC accordingly. ' (Site from Safety).               | (b) (4), (b) (6)              | 07 Apr 2021 19:01:29 |
| User signature succeeded.  | Judith Martin (b) (4)         | 31 Mar 2021 19:46:35 |
| User entered '26 Mar 2021'   | Lisa Vavro (b) (4)<br>(b) (4) | 31 Mar 2021 15:34:14 |

**US3802074**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:55:48**

[Start time \(00:00-23:59\)](#)

| Audit                     | User                                     | Time (GMT)           |
|---------------------------|--|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)                         | 15 Apr 2021 14:07:43 |
| User signature succeeded. | Judith Martin (b) (4)                    | 31 Mar 2021 19:46:35 |
| User entered empty.       | (b) (4)<br>Lisa Vavro (b) (4)<br>(b) (4) | 31 Mar 2021 15:34:14 |



**US3802074**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:55:48**

[AE start date and time \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 31 Mar 2021 15:34:14 |

**US3802074**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:55:48**

[Ongoing?](#)

| Audit                     | User                                     | Time (GMT)           |
|---------------------------|--|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)                         | 15 Apr 2021 14:07:45 |
| User signature succeeded. | Judith Martin (b) (4)                    | 31 Mar 2021 19:46:35 |
| User entered 'No (N)'     | (b) (4)<br>Lisa Vavro (b) (4)<br>(b) (4) | 31 Mar 2021 15:34:14 |

**US3802074**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:55:48**

*If not Ongoing, end date (dd MMM yyyy)*

| Audit                      | User                                     | Time (GMT)           |
|----------------------------|--|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                         | 15 Apr 2021 14:07:49 |
| User signature succeeded.  | Judith Martin (b) (4)                    | 31 Mar 2021 19:46:35 |
| User entered '29 Mar 2021' | (b) (4)<br>Lisa Vavro (b) (4)<br>(b) (4) | 31 Mar 2021 15:34:14 |

**US3802074**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:55:48**

**End time (00:00-23:59)**

| Audit                     | User                                     | Time (GMT)           |
|---------------------------|--|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)                         | 15 Apr 2021 14:07:50 |
| User signature succeeded. | Judith Martin (b) (4)                    | 31 Mar 2021 19:46:35 |
| User entered empty.       | (b) (4)<br>Lisa Vavro (b) (4)<br>(b) (4) | 31 Mar 2021 15:34:14 |

**US3802074**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:55:48**

[AE End Date and Time \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 31 Mar 2021 15:34:14 |

**US3802074**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:55:48**

[Severity](#)

| Audit  | User                          | Time (GMT)           |
|--|-------------------------------|----------------------|
| DataPoint Verified.                            | (b) (4), (b) (6)              | 15 Apr 2021 14:07:52 |
| User signature succeeded.                      | Judith Martin (b) (4)         | 31 Mar 2021 19:46:35 |
| User entered 'Grade 3/Severe (Grade 3/Severe)' | (b) (4)<br>Lisa Vavro (b) (4) | 31 Mar 2021 15:34:14 |

US3802074

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:55:48

[Is the adverse event serious?](#)

| Audit  | User                          | Time (GMT)           |
|--|-------------------------------|----------------------|
| DataPoint Verified.  | (b) (4), (b) (6)              | 15 Apr 2021 14:07:54 |
| User signature succeeded.  | Judith Martin (b) (4)         | 31 Mar 2021 19:46:35 |
| 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). | (b) (4)<br>System             | 31 Mar 2021 15:35:28 |
| 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                        | 31 Mar 2021 15:34:14 |
| User entered 'Yes (Y)'   | Lisa Vavro (b) (4)<br>(b) (4) | 31 Mar 2021 15:34:14 |

**US3802074**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:55:48**

[Death](#)

| Audit                     | User                                     | Time (GMT)           |
|---------------------------|--|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)                         | 15 Apr 2021 14:08:00 |
| User signature succeeded. | Judith Martin (b) (4)                    | 31 Mar 2021 19:46:35 |
| User entered '0'          | (b) (4)<br>Lisa Vavro (b) (4)<br>(b) (4) | 31 Mar 2021 15:34:14 |



**US3802074**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:55:48**

[Life threatening](#)

| Audit                     | User                                     | Time (GMT)           |
|---------------------------|--|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)                         | 15 Apr 2021 14:08:03 |
| User signature succeeded. | Judith Martin (b) (4)                    | 31 Mar 2021 19:46:35 |
| User entered '0'          | (b) (4)<br>Lisa Vavro (b) (4)<br>(b) (4) | 31 Mar 2021 15:34:14 |

US3802074

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:55:48

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit  | User                  | Time (GMT)           |
|--|-----------------------|----------------------|
| DataPoint Verified.  | (b) (4), (b) (6)      | 15 Apr 2021 14:08:09 |
| User signature succeeded.  | Judith Martin (b) (4) | 31 Mar 2021 19:46:35 |
| User closed query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).             | (b) (4)               | 31 Mar 2021 15:35:28 |
| 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). |                       | 31 Mar 2021 15:35:28 |
| User entered '1' reason for change: Data Entry Error   | Lisa Vavro (b) (4)    | 31 Mar 2021 15:35:28 |
| 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)               | 31 Mar 2021 15:34:14 |
| User entered '0'   | System                | 31 Mar 2021 15:34:14 |
|  | Lisa Vavro (b) (4)    | 31 Mar 2021 15:34:14 |
|  | (b) (4)               |                      |

**US3802074**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:55:48**

[Hospital Admission Date \(dd MMM yyyy\)](#)

| Audit                      | User                                     | Time (GMT)           |
|----------------------------|--|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                         | 15 Apr 2021 14:08:06 |
| User signature succeeded.  | Judith Martin (b) (4)                    | 31 Mar 2021 19:46:35 |
| User entered '27 Mar 2021' | (b) (4)<br>Lisa Vavro (b) (4)<br>(b) (4) | 31 Mar 2021 15:34:14 |

**US3802074**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:55:48**

**Hospital Discharge Date (dd MMM yyyy)**

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)      | 15 Apr 2021 14:08:13 |
| User signature succeeded.  | Judith Martin (b) (4) | 31 Mar 2021 19:46:35 |
| User entered '29 Mar 2021' | Lisa Vavro (b) (4)    | 31 Mar 2021 15:34:14 |

**US3802074**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:55:48**

[Admitted to ICU?](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)      | 15 Apr 2021 14:08:15 |
| User signature succeeded. | Judith Martin (b) (4) | 31 Mar 2021 19:46:35 |
| User entered 'No (N)'     | Lisa Vavro (b) (4)    | 31 Mar 2021 15:34:14 |

**US3802074**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:55:48**

[Number of Days in ICU](#)

| Audit                     | User                                     | Time (GMT)           |
|---------------------------|--|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)                         | 15 Apr 2021 14:08:17 |
| User signature succeeded. | Judith Martin (b) (4)                    | 31 Mar 2021 19:46:35 |
| User entered empty.       | (b) (4)<br>Lisa Vavro (b) (4)<br>(b) (4) | 31 Mar 2021 15:34:14 |

**US3802074**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:55:48**

[Persistent or significant disability or incapacity](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)      | 15 Apr 2021 14:08:19 |
| User signature succeeded. | Judith Martin (b) (4) | 31 Mar 2021 19:46:35 |
| User entered '0'          | Lisa Vavro (b) (4)    | 31 Mar 2021 15:34:14 |

**US3802074**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:55:48**

[Congenital anomaly or birth defect](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)      | 15 Apr 2021 14:08:21 |
| User signature succeeded. | Judith Martin (b) (4) | 31 Mar 2021 19:46:35 |
| User entered '0'          | Lisa Vavro (b) (4)    | 31 Mar 2021 15:34:14 |



**US3802074**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:55:48**

[Other medically important event](#)

| Audit                     | User                                     | Time (GMT)           |
|---------------------------|--|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)                         | 15 Apr 2021 14:08:23 |
| User signature succeeded. | Judith Martin (b) (4)                    | 31 Mar 2021 19:46:35 |
| User entered '0'          | (b) (4)<br>Lisa Vavro (b) (4)<br>(b) (4) | 31 Mar 2021 15:34:14 |

US3802074

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:55:48

[Relationship to investigational product](#)

| Audit   | User                     | Time (GMT)           |
|---|--------------------------|----------------------|
| DataPoint Verified.                                   | (b) (4), (b) (6)         | 19 Apr 2021 20:00:22 |
| User signature succeeded.                             | Judith Martin (b) (4)    | 19 Apr 2021 17:42:02 |
| DataPoint Un-verified.                                | (b) (4)                  |                      |
|   | Emily Carney (b) (4)     | 19 Apr 2021 12:16:20 |
|   | (b) (4)                  |                      |
| Signature has been broken.                            | Emily Carney (b) (4)     | 19 Apr 2021 12:16:20 |
|   | (b) (4)                  |                      |
| User entered 'Not Related (NOT RELATED)'              | Emily Carney (b) (4)     | 19 Apr 2021 12:16:20 |
| reason for change: Data Entry Error                   | (b) (4)                  |                      |
| DataPoint Verified.                                   | (b) (4), (b) (6)         | 15 Apr 2021 14:08:25 |
|   |                          |                      |
| User signature succeeded.                             | Judith Martin (b) (4)    | 08 Apr 2021 18:35:41 |
|   | (b) (4)                  |                      |
| User closed query 'PV Query: EDC shows                | (b) (4), (b) (6)         | 08 Apr 2021 16:40:47 |
| relationship to study drug and study procedure as not |                          |                      |
| related but SAE paper form shows as not applicable.   |                          |                      |
| Please confirm causality assessment in EDC            |                          |                      |
| accordingly. ' (Site from Safety).                    |                          |                      |
| Query 'PV Query: EDC shows relationship to study      | Melissa Andrasko (b) (4) | 07 Apr 2021 20:13:08 |
| drug and study procedure as not related but SAE       |                          |                      |
| paper form shows as not applicable. Please confirm    |                          |                      |
| causality assessment in EDC accordingly. ' answered   |                          |                      |
| with 'updated' (Site from Safety).                    |                          |                      |
| Signature has been broken.                            | Melissa Andrasko (b) (4) | 07 Apr 2021 20:12:01 |
|   |                          |                      |
| User entered 'Not Applicable (NOT APPLICABLE)'        | Melissa Andrasko (b) (4) | 07 Apr 2021 20:12:01 |
| reason for change: Data Entry Error                   |                          |                      |
|   |                          |                      |
| User opened query 'PV Query: EDC shows                | (b) (4), (b) (6)         | 07 Apr 2021 19:02:10 |
| relationship to study drug and study procedure as not |                          |                      |
| related but SAE paper form shows as not applicable.   |                          |                      |
| Please confirm causality assessment in EDC            |                          |                      |
| accordingly. ' (Site from Safety).                    |                          |                      |
| User signature succeeded.                             | Judith Martin (b) (4)    | 31 Mar 2021 19:46:35 |
|   | (b) (4)                  |                      |
| User entered 'Not Related (NOT RELATED)'              | Lisa Vavro (b) (4)       | 31 Mar 2021 15:34:14 |
|   | (b) (4)                  |                      |

US3802074

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:55:48

[Relationship to Study Procedure](#)

| Audit                                    | User                                     | Time (GMT)           |
|--|--|----------------------|
| DataPoint Verified.                      | (b) (4), (b) (6)                         | 15 Apr 2021 14:08:27 |
| User signature succeeded.                | Judith Martin (b) (4)                    | 31 Mar 2021 19:46:35 |
| User entered 'Not Related (NOT RELATED)' | (b) (4)<br>Lisa Vavro (b) (4)<br>(b) (4) | 31 Mar 2021 15:34:14 |

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:55:48

Action taken with investigational product

| Audit  | User                     | Time (GMT)           |
|--|--------------------------|----------------------|
| DataPoint Verified.                            | (b) (4), (b) (6)         | 15 Apr 2021 14:08:28 |
| User signature succeeded.                      | Judith Martin (b) (4)    | 06 Apr 2021 15:48:46 |
| Signature has been broken.                     | (b) (4)                  |                      |
|  | Melissa Andrasko (b) (4) | 05 Apr 2021 14:49:58 |
|  |                          |                      |
| User entered 'Not Applicable (NOT APPLICABLE)' | Melissa Andrasko (b) (4) | 05 Apr 2021 14:49:58 |
| reason for change: Data Entry Error            |                          |                      |
|  |                          |                      |
| User signature succeeded.                      | Judith Martin (b) (4)    | 31 Mar 2021 19:46:35 |
|  | (b) (4)                  |                      |
| User entered 'None (NONE)'                     | Lisa Vavro (b) (4)       | 31 Mar 2021 15:34:14 |
|  | (b) (4)                  |                      |

**US3802074**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:55:48**

[None](#)

| Audit                     | User                                     | Time (GMT)           |
|---------------------------|--|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)                         | 15 Apr 2021 14:08:30 |
| User signature succeeded. | Judith Martin (b) (4)                    | 31 Mar 2021 19:46:35 |
| User entered '0'          | (b) (4)<br>Lisa Vavro (b) (4)<br>(b) (4) | 31 Mar 2021 15:34:14 |

**US3802074**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:55:48**

[Concomitant Medication](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)      | 15 Apr 2021 14:08:32 |
| User signature succeeded. | Judith Martin (b) (4) | 31 Mar 2021 19:46:35 |
| User entered 'I'          | Lisa Vavro (b) (4)    | 31 Mar 2021 15:34:14 |

**US3802074**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:55:48**

[Concomitant Procedure](#)

| Audit                     | User                                     | Time (GMT)           |
|---------------------------|--|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)                         | 15 Apr 2021 14:08:34 |
| User signature succeeded. | Judith Martin (b) (4)                    | 31 Mar 2021 19:46:35 |
| User entered 'I'          | (b) (4)<br>Lisa Vavro (b) (4)<br>(b) (4) | 31 Mar 2021 15:34:14 |

US3802074

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:55:48

[Outcome](#)

| Audit   | User                     | Time (GMT)           |
|---|--------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)         | 15 Apr 2021 14:08:36 |
| User closed query 'PV Query: EDC shows event outcome as recovered/resolved but SAE paper form shows recovering/resolving. Please confirm outcome in EDC accordingly. ' (Site from Safety).                                  |                          | 08 Apr 2021 16:40:51 |
| Query 'PV Query: EDC shows event outcome as recovered/resolved but SAE paper form shows recovering/resolving. Please confirm outcome in EDC accordingly. ' answered with 'Participant is now recovered' (Site from Safety). | Melissa Andrasko (b) (4) | 07 Apr 2021 20:13:33 |
| User opened query 'PV Query: EDC shows event outcome as recovered/resolved but SAE paper form shows recovering/resolving. Please confirm outcome in EDC accordingly. ' (Site from Safety).                                  | (b) (4), (b) (6)         | 07 Apr 2021 19:01:45 |
| User signature succeeded.   | Judith Martin (b) (4)    | 31 Mar 2021 19:46:35 |
| User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'  | Lisa Vavro (b) (4)       | 31 Mar 2021 15:34:14 |



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Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:55:48

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

| Audit                     | User                                     | Time (GMT)           |
|---------------------------|--|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)                         | 15 Apr 2021 14:08:38 |
| User signature succeeded. | Judith Martin (b) (4)                    | 31 Mar 2021 19:46:35 |
| User entered empty.       | (b) (4)<br>Lisa Vavro (b) (4)<br>(b) (4) | 31 Mar 2021 15:34:14 |

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:55:48

[Narrative](#)

| Audit  | User                  | Time (GMT)           |
|--|-----------------------|----------------------|
| User closed query 'PV Query: Source from 07 Apr 2021 shows investigator causality for study drug as "Not applicable", previously provided as "Not related". Please confirm. ' (Site from Safety).  | (b) (4), (b) (6)      | 19 Apr 2021 21:16:16 |
| User closed query 'Re-Query: PV Query: Please provide laboratory units and reference ranges. If unavailable, please indicate so. ' (Site from Safety).   |                       | 19 Apr 2021 21:16:13 |
| DataPoint Verified.  |                       | 19 Apr 2021 19:59:18 |
| User signature succeeded.  | Judith Martin (b) (4) | 19 Apr 2021 17:42:02 |
| DataPoint Un-verified.   | (b) (4)               |                      |
|  | Emily Carney (b) (4)  | 19 Apr 2021 12:18:27 |
|  | (b) (4)               |                      |
| Signature has been broken.   | Emily Carney (b) (4)  | 19 Apr 2021 12:18:27 |
|  | (b) (4)               |                      |
| User entered 'PARTICIPANT EXPERIENCED INCREASED ABDOMINAL PAIN ON 26/MAR/2021. HE WAS EVALUATED AT THE ED ON 27/MAR/2021 AND ADMITTED FOR OBSERVATION. HE HAD SURGERY, CHOLECYSTECTOMY, ON 28/MAR/2021. HE WAS DISCHARGED FROM HOSPITAL WITHOUT COMPLICATIONS ON 29/MAR/2021. Laboratory units unavailable.' reason for change: Data Entry Error | Emily Carney (b) (4)  | 19 Apr 2021 12:18:27 |
|  | (b) (4)               |                      |
| Query 'Re-Query: PV Query: Please provide laboratory units and reference ranges. If unavailable, please indicate so. ' answered with 'Laboratory units unavailable. ' (Site from Safety).  | Emily Carney (b) (4)  | 19 Apr 2021 12:17:56 |
|  | (b) (4)               |                      |
| Query 'PV Query: Source from 07 Apr 2021 shows investigator causality for study drug as "Not applicable", previously provided as "Not related". Please confirm. ' answered with 'updated' (Site from Safety).  | Emily Carney (b) (4)  | 19 Apr 2021 12:17:19 |
|  | (b) (4)               |                      |
| User opened query 'PV Query: Source from 07 Apr 2021 shows investigator causality for study drug as "Not applicable", previously provided as "Not related". Please confirm. ' (Site from Safety).  | (b) (4), (b) (6)      | 16 Apr 2021 21:18:50 |
| User opened query 'Re-Query: PV Query: Please provide laboratory units and reference ranges. If unavailable, please indicate so. ' (Site from Safety).   |                       | 16 Apr 2021 21:18:42 |

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:55:48

[Narrative](#)

| Audit  | User                     | Time (GMT)           |
|--|--------------------------|----------------------|
| DataPoint Verified.  | (b) (4), (b) (6)         | 15 Apr 2021 14:08:40 |
| User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so. ' (Site from Safety).  |                          | 08 Apr 2021 16:40:58 |
| User closed query 'PV Query: Please provide laboratory units and reference ranges. If unavailable, please indicate so. ' (Site from Safety).   |                          | 08 Apr 2021 16:40:55 |
| Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so. ' answered with 'Covid testing was not performed' (Site from Safety).  | Melissa Andrasko (b) (4) | 07 Apr 2021 20:16:21 |
| Query 'PV Query: Please provide laboratory units and reference ranges. If unavailable, please indicate so. ' answered with 'All reference ranges and units were attached to the SAE form. ' (Site from Safety).  | Melissa Andrasko (b) (4) | 07 Apr 2021 20:15:44 |
| User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so. ' (Site from Safety).  | (b) (4), (b) (6)         | 07 Apr 2021 19:02:36 |
| User opened query 'PV Query: Please provide laboratory units and reference ranges. If unavailable, please indicate so. ' (Site from Safety).   |                          | 07 Apr 2021 19:02:30 |
| User signature succeeded.  | Judith Martin (b) (4)    | 01 Apr 2021 19:12:08 |
| Signature has been broken.   | Melissa Andrasko (b) (4) | 01 Apr 2021 15:24:18 |
| User entered 'PARTICIPANT EXPERIENCED INCREASED ABDOMINAL PAIN ON 26/MAR/2021. HE WAS EVALUATED AT THE ED ON 27/MAR/2021 AND ADMITTED FOR OBSERVATION. HE HAD SURGERY, CHOLECYSTECTOMY, ON 28/MAR/2021. HE WAS DISCHARGED FROM HOSPITAL WITHOut COMPLICATIONS ON 29/MAR/2021.' reason for change: Data Entry Error | Melissa Andrasko (b) (4) | 01 Apr 2021 15:24:18 |

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3802074

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:55:48

[Narrative](#)

| Audit   | User                          | Time (GMT)           |
|---|-------------------------------|----------------------|
| User signature succeeded.   | Judith Martin (b) (4)         | 31 Mar 2021 19:46:35 |
| User entered 'Participant experienced increased abdominal pain on 26/Mar/2021. He was evaluated at the ED on 27/Mar/2021 and admitted for observation. He had surgery, cholecystectomy, on 28/Mar/2021. He was discharged from hospital with complications on 29/Mar/2021.' | (b) (4)<br>Lisa Vavro (b) (4) | 31 Mar 2021 15:34:14 |

**US3802074**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:55:48**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered 'I' | System | 31 Mar 2021 15:34:14 |

**US3802074**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:55:48**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered 'I' | System | 31 Mar 2021 15:34:14 |

**US3802074**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:55:48**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '0' | System | 31 Mar 2021 15:34:14 |

US3802074

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:55:48

[Adverse event](#)

| Audit   | User                     | Time (GMT)           |
|---|--------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)         | 15 Apr 2021 14:08:52 |
| User signature succeeded.   | Judith Martin (b) (4)    | 08 Apr 2021 18:35:41 |
| User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension worsened - version MedDRA\\23.0. | Coder Import (b) (4)     | 07 Apr 2021 14:23:34 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.  | Coder Import (b) (4)     | 07 Apr 2021 14:23:34 |
| Data point term sent to Coder   | System                   | 07 Apr 2021 14:22:46 |
| User entered 'worsening hypertension'   | Melissa Andrasko (b) (4) | 07 Apr 2021 14:22:07 |



US3802074

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:55:48

[Was this a medically-attended AE?](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)                    | 15 Apr 2021 14:08:54 |
| User signature succeeded. | Judith Martin (b) (4)               | 08 Apr 2021 18:35:41 |
| User entered 'Yes (Y)'    | (b) (4)<br>Melissa Andrasko (b) (4) | 07 Apr 2021 14:22:07 |

**US3802074**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:55:48**

[Was this a Solicited Adverse Reaction?](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)                    | 15 Apr 2021 14:08:56 |
| User signature succeeded. | Judith Martin (b) (4)               | 08 Apr 2021 18:35:41 |
| User entered 'No (N)'     | (b) (4)<br>Melissa Andrasko (b) (4) | 07 Apr 2021 14:22:07 |

US3802074

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:55:48

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)                    | 15 Apr 2021 14:08:59 |
| User signature succeeded. | Judith Martin (b) (4)               | 08 Apr 2021 18:35:41 |
| User entered 'No (N)'     | (b) (4)<br>Melissa Andrasko (b) (4) | 07 Apr 2021 14:22:07 |

US3802074

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:55:48

Start date (dd MMM yyyy)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)         | 15 Apr 2021 14:09:00 |
| User signature succeeded.  | Judith Martin (b) (4)    | 08 Apr 2021 18:35:41 |
| User entered '01 Mar 2021' | (b) (4)                  |                      |
|                            | Melissa Andrasko (b) (4) | 07 Apr 2021 14:22:07 |
|                            |                          |                      |
|                            |                          |                      |

US3802074

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:55:48

Start time (00:00-23:59)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)         | 15 Apr 2021 14:09:02 |
| User signature succeeded. | Judith Martin (b) (4)    | 08 Apr 2021 18:35:41 |
| User entered empty.       | (b) (4)                  |                      |
|                           | Melissa Andrasko (b) (4) | 07 Apr 2021 14:22:07 |
|                           |                          |                      |
|                           |                          |                      |

**US3802074**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:55:48**

[AE start date and time \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 07 Apr 2021 14:22:07 |

**US3802074**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:55:48**

[Ongoing?](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)                    | 15 Apr 2021 14:09:04 |
| User signature succeeded. | Judith Martin (b) (4)               | 08 Apr 2021 18:35:41 |
| User entered 'Yes (Y)'    | (b) (4)<br>Melissa Andrasko (b) (4) | 07 Apr 2021 14:22:07 |

US3802074

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:55:48

If not Ongoing, end date (dd MMM yyyy)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)         | 15 Apr 2021 14:09:06 |
| User signature succeeded. | Judith Martin (b) (4)    | 08 Apr 2021 18:35:41 |
| User entered empty.       | (b) (4)                  |                      |
|                           | Melissa Andrasko (b) (4) | 07 Apr 2021 14:22:07 |
|                           |                          |                      |
|                           |                          |                      |



**US3802074**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:55:48**

[End time \(00:00-23:59\)](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)         | 15 Apr 2021 14:09:09 |
| User signature succeeded. | Judith Martin (b) (4)    | 08 Apr 2021 18:35:41 |
| User entered empty.       | (b) (4)                  |                      |
|                           | Melissa Andrasko (b) (4) | 07 Apr 2021 14:22:07 |
|                           |                          |                      |
|                           |                          |                      |

**US3802074**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:55:48**

[AE End Date and Time \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 07 Apr 2021 14:22:07 |

**US3802074**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:55:48**

[Severity](#)

| Audit  | User                             | Time (GMT)           |
|--|----------------------------------|----------------------|
| DataPoint Verified.                                | (b) (4), (b) (6)                 | 15 Apr 2021 14:09:10 |
| User signature succeeded.                          | Judith Martin (b) (4)            | 08 Apr 2021 18:35:41 |
| User entered 'Grade 2/Moderate (Grade 2/Moderate)' | (b) (4) Melissa Andrasko (b) (4) | 07 Apr 2021 14:22:07 |

US3802074

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:55:48

[Is the adverse event serious?](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)                    | 15 Apr 2021 14:09:12 |
| User signature succeeded. | Judith Martin (b) (4)               | 08 Apr 2021 18:35:41 |
| User entered 'No (N)'     | (b) (4)<br>Melissa Andrasko (b) (4) | 07 Apr 2021 14:22:07 |

**US3802074**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:55:48**

[Death](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)                    | 15 Apr 2021 14:09:15 |
| User signature succeeded. | Judith Martin (b) (4)               | 08 Apr 2021 18:35:41 |
| User entered '0'          | (b) (4)<br>Melissa Andrasko (b) (4) | 07 Apr 2021 14:22:07 |

**US3802074**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:55:48**

[Life threatening](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)                    | 15 Apr 2021 14:09:16 |
| User signature succeeded. | Judith Martin (b) (4)               | 08 Apr 2021 18:35:41 |
| User entered '0'          | (b) (4)<br>Melissa Andrasko (b) (4) | 07 Apr 2021 14:22:07 |

**US3802074**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:55:48**

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)                    | 15 Apr 2021 14:09:18 |
| User signature succeeded. | Judith Martin (b) (4)               | 08 Apr 2021 18:35:41 |
| User entered '0'          | (b) (4)<br>Melissa Andrasko (b) (4) | 07 Apr 2021 14:22:07 |

US3802074

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:55:48

Hospital Admission Date (*dd MMM yyyy*)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)         | 15 Apr 2021 14:09:20 |
| User signature succeeded. | Judith Martin (b) (4)    | 08 Apr 2021 18:35:41 |
| User entered empty.       | (b) (4)                  |                      |
|                           | Melissa Andrasko (b) (4) | 07 Apr 2021 14:22:07 |
|                           |                          |                      |
|                           |                          |                      |



US3802074

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:55:48

Hospital Discharge Date (dd MMM yyyy)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)         | 15 Apr 2021 14:09:22 |
| User signature succeeded. | Judith Martin (b) (4)    | 08 Apr 2021 18:35:41 |
| User entered empty.       | (b) (4)                  |                      |
|                           | Melissa Andrasko (b) (4) | 07 Apr 2021 14:22:07 |
|                           |                          |                      |
|                           |                          |                      |

**US3802074**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:55:48**

[Admitted to ICU?](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)         | 15 Apr 2021 14:09:24 |
| User signature succeeded. | Judith Martin (b) (4)    | 08 Apr 2021 18:35:41 |
| User entered empty.       | (b) (4)                  |                      |
|                           | Melissa Andrasko (b) (4) | 07 Apr 2021 14:22:07 |
|                           |                          |                      |
|                           |                          |                      |

US3802074

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:55:48

[Number of Days in ICU](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)         | 15 Apr 2021 14:09:26 |
| User signature succeeded. | Judith Martin (b) (4)    | 08 Apr 2021 18:35:41 |
| User entered empty.       | (b) (4)                  |                      |
|                           | Melissa Andrasko (b) (4) | 07 Apr 2021 14:22:07 |
|                           |                          |                      |
|                           |                          |                      |

**US3802074**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:55:48**

[Persistent or significant disability or incapacity](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)                    | 15 Apr 2021 14:09:27 |
| User signature succeeded. | Judith Martin (b) (4)               | 08 Apr 2021 18:35:41 |
| User entered '0'          | (b) (4)<br>Melissa Andrasko (b) (4) | 07 Apr 2021 14:22:07 |

US3802074

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:55:48

[Congenital anomaly or birth defect](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)                    | 15 Apr 2021 14:09:29 |
| User signature succeeded. | Judith Martin (b) (4)               | 08 Apr 2021 18:35:41 |
| User entered '0'          | (b) (4)<br>Melissa Andrasko (b) (4) | 07 Apr 2021 14:22:07 |

US3802074

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:55:48

[Other medically important event](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)                    | 15 Apr 2021 14:09:31 |
| User signature succeeded. | Judith Martin (b) (4)               | 08 Apr 2021 18:35:41 |
| User entered '0'          | (b) (4)<br>Melissa Andrasko (b) (4) | 07 Apr 2021 14:22:07 |

US3802074

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:55:48

[Relationship to investigational product](#)

| Audit                                    | User                                | Time (GMT)           |
|--|-------------------------------------|----------------------|
| DataPoint Verified.                      | (b) (4), (b) (6)                    | 15 Apr 2021 14:09:33 |
| User signature succeeded.                | Judith Martin (b) (4)               | 08 Apr 2021 18:35:41 |
| User entered 'Not Related (NOT RELATED)' | (b) (4)<br>Melissa Andrasko (b) (4) | 07 Apr 2021 14:22:07 |

US3802074

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:55:48

[Relationship to Study Procedure](#)

| Audit                                    | User                                | Time (GMT)           |
|--|-------------------------------------|----------------------|
| DataPoint Verified.                      | (b) (4), (b) (6)                    | 15 Apr 2021 14:09:34 |
| User signature succeeded.                | Judith Martin (b) (4)               | 08 Apr 2021 18:35:41 |
| User entered 'Not Related (NOT RELATED)' | (b) (4)<br>Melissa Andrasko (b) (4) | 07 Apr 2021 14:22:07 |



**US3802074**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:55:48**

[Action taken with investigational product](#)

| Audit  | User                     | Time (GMT)           |
|--|--------------------------|----------------------|
| DataPoint Verified.                            | (b) (4), (b) (6)         | 15 Apr 2021 14:09:36 |
| User signature succeeded.                      | Judith Martin (b) (4)    | 08 Apr 2021 18:35:41 |
| User entered 'Not Applicable (NOT APPLICABLE)' | (b) (4)                  |                      |
|  | Melissa Andrasko (b) (4) | 07 Apr 2021 14:22:07 |
|  |                          |                      |
|  |                          |                      |

**US3802074**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:55:48**

[None](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)                    | 15 Apr 2021 14:09:37 |
| User signature succeeded. | Judith Martin (b) (4)               | 08 Apr 2021 18:35:41 |
| User entered '0'          | (b) (4)<br>Melissa Andrasko (b) (4) | 07 Apr 2021 14:22:07 |

US3802074

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:55:48

[Concomitant Medication](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)                    | 15 Apr 2021 14:09:40 |
| User signature succeeded. | Judith Martin (b) (4)               | 08 Apr 2021 18:35:41 |
| User entered 'I'          | (b) (4)<br>Melissa Andrasko (b) (4) | 07 Apr 2021 14:22:07 |

US3802074

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:55:48

[Concomitant Procedure](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)                    | 15 Apr 2021 14:09:42 |
| User signature succeeded. | Judith Martin (b) (4)               | 08 Apr 2021 18:35:41 |
| User entered '0'          | (b) (4)<br>Melissa Andrasko (b) (4) | 07 Apr 2021 14:22:07 |

**US3802074**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:55:48**

[Outcome](#)

| Audit  | User                                | Time (GMT)           |
|--|-------------------------------------|----------------------|
| DataPoint Verified.  | (b) (4), (b) (6)                    | 15 Apr 2021 14:09:44 |
| User signature succeeded.                                  | Judith Martin (b) (4)               | 08 Apr 2021 18:35:41 |
| User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' | (b) (4)<br>Melissa Andrasko (b) (4) | 07 Apr 2021 14:22:07 |

US3802074

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:55:48

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)         | 15 Apr 2021 14:09:46 |
| User signature succeeded. | Judith Martin (b) (4)    | 08 Apr 2021 18:35:41 |
| User entered empty.       | (b) (4)                  |                      |
|                           | Melissa Andrasko (b) (4) | 07 Apr 2021 14:22:07 |
|                           |                          |                      |
|                           |                          |                      |

**US3802074**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:55:48**

[Narrative](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)         | 15 Apr 2021 14:09:48 |
| User signature succeeded. | Judith Martin (b) (4)    | 08 Apr 2021 18:35:41 |
| User entered empty.       | (b) (4)                  |                      |
|                           | Melissa Andrasko (b) (4) | 07 Apr 2021 14:22:07 |
|                           |                          |                      |
|                           |                          |                      |

**US3802074**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:55:48**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '0' | System | 07 Apr 2021 14:22:07 |



**US3802074**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:55:48**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 07 Apr 2021 14:22:07 |

US3802074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 09:55:48

Were any prior/concomitant medications and/or vaccinations taken?

| Audit  | User  | Time (GMT)   |
|--|---|--|
| Data hard locked.  | (b) (4), (b) (6)  | 03 May 2021 05:57:44   |
| DataPoint Verified.  |   | 19 Apr 2021 19:17:53   |
| User closed query 'Per DM CLR: Per Diary Dose 2 Day 1 (28SEP2020), Headache (General) = Any use of prescription pain reliever or prevents daily activity, however, there is no corresponding Con Med recorded that matches this indication (HEADACHE) within this timeframe. Please reconcile and update the Con Med eCRF to record the medication given as appropriate, otherwise clarify.' (Site from DM). Query 'Per DM CLR: Per Diary Dose 2 Day 1 (28SEP2020), Headache (General) = Any use of prescription pain reliever or prevents daily activity, however, there is no corresponding Con Med recorded that matches this indication (HEADACHE) within this timeframe. Please reconcile and update the Con Med eCRF to record the medication given as appropriate, otherwise clarify.' answered with 'participant was taking advil to relieve symptoms of injection site pain and headache.' (Site from DM). User opened query 'Per DM CLR: Per Diary Dose 2 Day 1 (28SEP2020), Headache (General) = Any use of prescription pain reliever or prevents daily activity, however, there is no corresponding Con Med recorded that matches this indication (HEADACHE) within this timeframe. Please reconcile and update the Con Med eCRF to record the medication given as appropriate, otherwise clarify.' (Site from DM). User signature succeeded. | Lalicia Roman (b) (4)<br>(b) (4)  | 11 Feb 2021 21:09:08   |
| User entered 'Yes (Y)'   | (b) (4), (b) (6)<br><br>Judith Martin (b) (4)<br>(b) (4)<br>Dominic Kramer (b) (4)<br>(b) (4) | 31 Jan 2021 03:30:41<br><br>28 Jan 2021 18:19:31<br>31 Aug 2020 13:56:04 |

US3802074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:55:48

Name of Medication

| Audit  | User                                       | Time (GMT)           |
|--|--|----------------------|
| DataPoint Verified.  | (b) (4), (b) (6)                           | 19 Apr 2021 20:24:39 |
| User signature succeeded.  | Judith Martin (b) (4)                      | 28 Jan 2021 18:19:31 |
| User coded data point as ATC:<br>CARDIOVASCULAR SYSTEM, ATC: BETA<br>BLOCKING AGENTS, ATC: BETA BLOCKING<br>AGENTS, ATC: BETA BLOCKING AGENTS,<br>SELECTIVE, PRODUCT: ATENOLOL - version<br>WHODrug-Global-B3\\202003. | (b) (4)<br>Coder Import (b) (4)<br>(b) (4) | 31 Aug 2020 13:58:50 |
| 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)            | 31 Aug 2020 13:58:50 |
| Data point term sent to Coder  | System                                     | 31 Aug 2020 13:58:11 |
| User entered 'Atenolol'  | Dominic Kramer (b) (4)<br>(b) (4)          | 31 Aug 2020 13:57:32 |

**US3802074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:55:48**

[Prophylaxis](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)                  | 19 Apr 2021 20:24:45 |
| User signature succeeded. | Judith Martin (b) (4)<br>(b) (4)  | 28 Jan 2021 18:19:31 |
| User entered 'No (N)'     | Dominic Kramer (b) (4)<br>(b) (4) | 31 Aug 2020 13:57:32 |

**US3802074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:55:48**

[Indication](#)

| Audit                       | User                              | Time (GMT)           |
|-----------------------------|-----------------------------------|----------------------|
| DataPoint Verified.         | (b) (4), (b) (6)                  | 19 Apr 2021 20:24:41 |
| User signature succeeded.   | Judith Martin (b) (4)<br>(b) (4)  | 28 Jan 2021 18:19:31 |
| User entered 'Hypertension' | Dominic Kramer (b) (4)<br>(b) (4) | 31 Aug 2020 13:57:32 |

**US3802074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:55:48**

[Dose per administration](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)                  | 19 Apr 2021 20:24:47 |
| User signature succeeded. | Judith Martin (b) (4)<br>(b) (4)  | 28 Jan 2021 18:19:31 |
| User entered '50'         | Dominic Kramer (b) (4)<br>(b) (4) | 31 Aug 2020 13:57:32 |

**US3802074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:55:48**

[Dose unit](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)                  | 19 Apr 2021 20:24:49 |
| User signature succeeded. | Judith Martin (b) (4)<br>(b) (4)  | 28 Jan 2021 18:19:31 |
| User entered 'mg (mg)'    | Dominic Kramer (b) (4)<br>(b) (4) | 31 Aug 2020 13:57:32 |

US3802074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:55:48

If dose unit is Other, specify

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)                  | 19 Apr 2021 20:24:51 |
| User signature succeeded. | Judith Martin (b) (4)<br>(b) (4)  | 28 Jan 2021 18:19:31 |
| User entered empty.       | Dominic Kramer (b) (4)<br>(b) (4) | 31 Aug 2020 13:57:32 |



US3802074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:55:48

[Frequency](#)

| Audit                          | User                              | Time (GMT)           |
|--------------------------------|-----------------------------------|----------------------|
| DataPoint Verified.            | (b) (4), (b) (6)                  | 19 Apr 2021 20:24:53 |
| User signature succeeded.      | Judith Martin (b) (4)<br>(b) (4)  | 28 Jan 2021 18:19:31 |
| User entered 'once daily (QD)' | Dominic Kramer (b) (4)<br>(b) (4) | 31 Aug 2020 13:57:32 |

US3802074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:55:48

If frequency is Other, specify

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)                  | 19 Apr 2021 20:24:55 |
| User signature succeeded. | Judith Martin (b) (4)<br>(b) (4)  | 28 Jan 2021 18:19:31 |
| User entered empty.       | Dominic Kramer (b) (4)<br>(b) (4) | 31 Aug 2020 13:57:32 |

**US3802074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:55:48**

[Route of administration](#)

| Audit                      | User                              | Time (GMT)           |
|----------------------------|-----------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                  | 19 Apr 2021 20:24:58 |
| User signature succeeded.  | Judith Martin (b) (4)<br>(b) (4)  | 28 Jan 2021 18:19:31 |
| User entered 'Oral (ORAL)' | Dominic Kramer (b) (4)<br>(b) (4) | 31 Aug 2020 13:57:32 |

US3802074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:55:48

If route of administration is Other, specify

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)                  | 19 Apr 2021 20:24:59 |
| User signature succeeded. | Judith Martin (b) (4)             | 28 Jan 2021 18:19:31 |
| User entered empty.       | (b) (4)<br>Dominic Kramer (b) (4) | 31 Aug 2020 13:57:32 |

**US3802074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:55:48**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                              | Time (GMT)           |
|----------------------------|-----------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                  | 19 Apr 2021 20:25:02 |
| User signature succeeded.  | Judith Martin (b) (4)<br>(b) (4)  | 28 Jan 2021 18:19:31 |
| User entered 'UN UNK 2005' | Dominic Kramer (b) (4)<br>(b) (4) | 31 Aug 2020 13:57:32 |

**US3802074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:55:48**

[Start date completely unknown](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)                  | 19 Apr 2021 20:25:04 |
| User signature succeeded. | Judith Martin (b) (4)<br>(b) (4)  | 28 Jan 2021 18:19:31 |
| User entered '0'          | Dominic Kramer (b) (4)<br>(b) (4) | 31 Aug 2020 13:57:32 |

**US3802074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:55:48**

[Ongoing?](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)                  | 19 Apr 2021 20:25:06 |
| User signature succeeded. | Judith Martin (b) (4)<br>(b) (4)  | 28 Jan 2021 18:19:31 |
| User entered 'Yes (Y)'    | Dominic Kramer (b) (4)<br>(b) (4) | 31 Aug 2020 13:57:32 |

US3802074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:55:48

If not Ongoing, End date (*dd MMM yyyy*)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)                  | 19 Apr 2021 20:25:08 |
| User signature succeeded. | Judith Martin (b) (4)<br>(b) (4)  | 28 Jan 2021 18:19:31 |
| User entered empty.       | Dominic Kramer (b) (4)<br>(b) (4) | 31 Aug 2020 13:57:32 |



US3802074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:55:48

[Was this medication taken for solicited event?](#)

| Audit  | User                              | Time (GMT)           |
|--|-----------------------------------|----------------------|
| DataPoint Verified.  | (b) (4), (b) (6)                  | 19 Apr 2021 20:25:10 |
| User signature succeeded.  | Judith Martin (b) (4)             | 28 Jan 2021 18:19:31 |
| User closed query 'Per DM CLR: Was this medication taken for solicited event? = YES, however, the noted indication is not one of the listed solicited events per protocol. Please confirm and update as appropriate, otherwise clarify.' (Site from DM).             | (b) (4)<br>(b) (4), (b) (6)       | 27 Oct 2020 16:59:34 |
| Query 'Per DM CLR: Was this medication taken for solicited event? = YES, however, the noted indication is not one of the listed solicited events per protocol. Please confirm and update as appropriate, otherwise clarify.' answered with 'Updated' (Site from DM). | Emily Carney (b) (4)<br>(b) (4)   | 21 Oct 2020 13:49:40 |
| User entered 'No (N)' reason for change: Data Entry Error  | Emily Carney (b) (4)<br>(b) (4)   | 21 Oct 2020 13:49:29 |
| User opened query 'Per DM CLR: Was this medication taken for solicited event? = YES, however, the noted indication is not one of the listed solicited events per protocol. Please confirm and update as appropriate, otherwise clarify.' (Site from DM).             | (b) (4), (b) (6)                  | 01 Oct 2020 14:36:11 |
| User entered 'Yes (Y)'   | Dominic Kramer (b) (4)<br>(b) (4) | 31 Aug 2020 13:57:32 |

**US3802074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:55:48**

[Separate Dosage Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 31 Aug 2020 13:57:32 |

**US3802074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:55:48**

[Interval Dosage Unit Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 31 Aug 2020 13:57:32 |

**US3802074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:55:48**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User   | Time (GMT)           |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 31 Aug 2020 13:57:32 |

US3802074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:55:48

[Name of Medication](#)

| Audit   | User                   | Time (GMT)           |
|---|------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)       | 19 Apr 2021 20:25:30 |
| User signature succeeded.   | Judith Martin (b) (4)  | 28 Jan 2021 18:19:31 |
| 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: SIMVASTATIN -<br>version WHODrug-Global-B3\\202003. | Coder Import (b) (4)   | 31 Aug 2020 14:00:05 |
| User coded data point as Term Coded data point by<br>User: Coder System - version<br>WHODrug-Global-B3\\202003.   | Coder Import (b) (4)   | 31 Aug 2020 14:00:05 |
| Data point term sent to Coder   | System                 | 31 Aug 2020 13:59:13 |
| User entered 'Simvastatin'  | Dominic Kramer (b) (4) | 31 Aug 2020 13:58:29 |

**US3802074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:55:48**

[Prophylaxis](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)                  | 19 Apr 2021 20:25:30 |
| User signature succeeded. | Judith Martin (b) (4)<br>(b) (4)  | 28 Jan 2021 18:19:31 |
| User entered 'No (N)'     | Dominic Kramer (b) (4)<br>(b) (4) | 31 Aug 2020 13:58:29 |

**US3802074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:55:48**

[Indication](#)

| Audit                           | User                              | Time (GMT)           |
|---------------------------------|-----------------------------------|----------------------|
| DataPoint Verified.             | (b) (4), (b) (6)                  | 19 Apr 2021 20:25:30 |
| User signature succeeded.       | Judith Martin (b) (4)<br>(b) (4)  | 28 Jan 2021 18:19:31 |
| User entered 'High Cholesterol' | Dominic Kramer (b) (4)<br>(b) (4) | 31 Aug 2020 13:58:29 |

**US3802074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:55:48**

[Dose per administration](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)                  | 19 Apr 2021 20:25:30 |
| User signature succeeded. | Judith Martin (b) (4)<br>(b) (4)  | 28 Jan 2021 18:19:31 |
| User entered '20'         | Dominic Kramer (b) (4)<br>(b) (4) | 31 Aug 2020 13:58:29 |



US3802074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:55:48

[Dose unit](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)                  | 19 Apr 2021 20:25:30 |
| User signature succeeded. | Judith Martin (b) (4)<br>(b) (4)  | 28 Jan 2021 18:19:31 |
| User entered 'mg (mg)'    | Dominic Kramer (b) (4)<br>(b) (4) | 31 Aug 2020 13:58:29 |

US3802074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:55:48

If dose unit is Other, specify

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)                  | 19 Apr 2021 20:25:30 |
| User signature succeeded. | Judith Martin (b) (4)             | 28 Jan 2021 18:19:31 |
| User entered empty.       | (b) (4)<br>Dominic Kramer (b) (4) | 31 Aug 2020 13:58:29 |

**US3802074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:55:48**

[Frequency](#)

| Audit                          | User                              | Time (GMT)           |
|--------------------------------|-----------------------------------|----------------------|
| DataPoint Verified.            | (b) (4), (b) (6)                  | 19 Apr 2021 20:25:30 |
| User signature succeeded.      | Judith Martin (b) (4)<br>(b) (4)  | 28 Jan 2021 18:19:31 |
| User entered 'once daily (QD)' | Dominic Kramer (b) (4)<br>(b) (4) | 31 Aug 2020 13:58:29 |

US3802074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:55:48

If frequency is Other, specify

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)                  | 19 Apr 2021 20:25:30 |
| User signature succeeded. | Judith Martin (b) (4)             | 28 Jan 2021 18:19:31 |
| User entered empty.       | (b) (4)<br>Dominic Kramer (b) (4) | 31 Aug 2020 13:58:29 |

**US3802074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:55:48**

[Route of administration](#)

| Audit                      | User                              | Time (GMT)           |
|----------------------------|-----------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                  | 19 Apr 2021 20:25:30 |
| User signature succeeded.  | Judith Martin (b) (4)<br>(b) (4)  | 28 Jan 2021 18:19:31 |
| User entered 'Oral (ORAL)' | Dominic Kramer (b) (4)<br>(b) (4) | 31 Aug 2020 13:58:29 |

US3802074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:55:48

If route of administration is Other, specify

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)                  | 19 Apr 2021 20:25:30 |
| User signature succeeded. | Judith Martin (b) (4)             | 28 Jan 2021 18:19:31 |
| User entered empty.       | (b) (4)<br>Dominic Kramer (b) (4) | 31 Aug 2020 13:58:29 |

US3802074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:55:48

Start date (dd MMM yyyy)

| Audit                      | User                              | Time (GMT)           |
|----------------------------|-----------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                  | 19 Apr 2021 20:25:30 |
| User signature succeeded.  | Judith Martin (b) (4)<br>(b) (4)  | 28 Jan 2021 18:19:31 |
| User entered 'UN UNK 2005' | Dominic Kramer (b) (4)<br>(b) (4) | 31 Aug 2020 13:58:29 |

**US3802074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:55:48**

[Start date completely unknown](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)                  | 19 Apr 2021 20:25:30 |
| User signature succeeded. | Judith Martin (b) (4)             | 28 Jan 2021 18:19:31 |
| User entered '0'          | (b) (4)<br>Dominic Kramer (b) (4) | 31 Aug 2020 13:58:29 |



**US3802074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:55:48**

[Ongoing?](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)                  | 19 Apr 2021 20:25:30 |
| User signature succeeded. | Judith Martin (b) (4)<br>(b) (4)  | 28 Jan 2021 18:19:31 |
| User entered 'Yes (Y)'    | Dominic Kramer (b) (4)<br>(b) (4) | 31 Aug 2020 13:58:29 |

US3802074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:55:48

If not Ongoing, End date (*dd MMM yyyy*)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)                  | 19 Apr 2021 20:25:30 |
| User signature succeeded. | Judith Martin (b) (4)             | 28 Jan 2021 18:19:31 |
| User entered empty.       | (b) (4)<br>Dominic Kramer (b) (4) | 31 Aug 2020 13:58:29 |

US3802074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:55:48

[Was this medication taken for solicited event?](#)

| Audit   | User                              | Time (GMT)           |
|---|-----------------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)                  | 19 Apr 2021 20:25:30 |
| User signature succeeded.   | Judith Martin (b) (4)             | 28 Jan 2021 18:19:31 |
| User closed query 'Per DM CLR: Was this medication taken for solicited event? = YES, however, the noted indication is not one of the listed solicited events per protocol. Please confirm and update as appropriate, otherwise clarify.' (Site from DM).              | (b) (4)<br>(b) (4), (b) (6)       | 27 Oct 2020 16:59:37 |
| Query 'Per DM CLR: Was this medication taken for solicited event? = YES, however, the noted indication is not one of the listed solicited events per protocol. Please confirm and update as appropriate, otherwise clarify.' answered with 'Updated ' (Site from DM). | Emily Carney (b) (4)<br>(b) (4)   | 21 Oct 2020 13:49:58 |
| User entered 'No (N)' reason for change: Data Entry Error   | Emily Carney (b) (4)<br>(b) (4)   | 21 Oct 2020 13:49:51 |
| User opened query 'Per DM CLR: Was this medication taken for solicited event? = YES, however, the noted indication is not one of the listed solicited events per protocol. Please confirm and update as appropriate, otherwise clarify.' (Site from DM).              | (b) (4), (b) (6)                  | 01 Oct 2020 14:36:27 |
| User entered 'Yes (Y)'  | Dominic Kramer (b) (4)<br>(b) (4) | 31 Aug 2020 13:58:29 |

**US3802074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:55:48**

[Separate Dosage Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 31 Aug 2020 13:58:29 |

**US3802074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:55:48**

[Interval Dosage Unit Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 31 Aug 2020 13:58:29 |

**US3802074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:55:48**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User   | Time (GMT)           |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 31 Aug 2020 13:58:29 |

US3802074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:55:48

Name of Medication

| Audit   | User                  | Time (GMT)           |
|---|-----------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)      | 19 Apr 2021 20:25:30 |
| User signature succeeded.   | Judith Martin (b) (4) | 06 Apr 2021 15:48:46 |
| User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: NASAL DECONGESTANTS FOR SYSTEMIC USE, ATC: SYMPATHOMIMETICS, PRODUCT: PSEUDOEPHEDRINE HYDROCHLORIDE, PRODUCTSYNONYM: SUDAFED [PSEUDOEPHEDRINE HYDROCHLORIDE] - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)  | 06 Apr 2021 12:29:53 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.   | Coder Import (b) (4)  | 06 Apr 2021 12:29:53 |
| Data point term sent to Coder   | System                | 06 Apr 2021 12:28:12 |
| User closed query 'CDM-Coding: Please enter the active ingredient(s) of drug name SUDAFED in drug name field and please make your changes to the reported term. Thank you.  | System                | 06 Apr 2021 12:27:52 |
| ' (Site from System).   |                       |                      |
| Query 'CDM-Coding: Please enter the active ingredient(s) of drug name SUDAFED in drug name field and please make your changes to the reported term. Thank you.  | Emily Carney (b) (4)  | 06 Apr 2021 12:27:52 |
| ' answered with 'updated' (Site from System).   |                       |                      |
| Coding entries removed.   | Emily Carney (b) (4)  | 06 Apr 2021 12:27:23 |
| Signature has been broken.  | Emily Carney (b) (4)  | 06 Apr 2021 12:27:23 |
| User entered 'SUDAFED (pseudoephedrine HCl)' reason for change: Data Entry Error  | Emily Carney (b) (4)  | 06 Apr 2021 12:27:23 |
| User opened query 'CDM-Coding: Please enter the active ingredient(s) of drug name SUDAFED in drug name field and please make your changes to the reported term. Thank you.  | Coder Import (b) (4)  | 06 Apr 2021 12:21:18 |
| ' (Site from System).   |                       |                      |
| User signature succeeded.   | Judith Martin (b) (4) | 28 Jan 2021 18:19:31 |

US3802074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:55:48

[Name of Medication](#)

| Audit   | User                   | Time (GMT)           |
|---|------------------------|----------------------|
| User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: NASAL DECONGESTANTS FOR SYSTEMIC USE, ATC: SYMPATHOMIMETICS, PRODUCT: PSEUDOEPHEDRINE HYDROCHLORIDE, PRODUCTSYNONYM: SUDAFED [PSEUDOEPHEDRINE HYDROCHLORIDE] - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)   | 31 Aug 2020 14:01:53 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.   | Coder Import (b) (4)   | 31 Aug 2020 14:01:53 |
| Data point term sent to Coder   | System                 | 31 Aug 2020 14:00:15 |
| User entered 'Sudafed'  | Dominic Kramer (b) (4) | 31 Aug 2020 13:59:39 |



**US3802074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:55:48**

[Prophylaxis](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)                  | 19 Apr 2021 20:25:30 |
| User signature succeeded. | Judith Martin (b) (4)<br>(b) (4)  | 28 Jan 2021 18:19:31 |
| User entered 'No (N)'     | Dominic Kramer (b) (4)<br>(b) (4) | 31 Aug 2020 13:59:39 |

**US3802074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:55:48**

[Indication](#)

| Audit                             | User                              | Time (GMT)           |
|-----------------------------------|-----------------------------------|----------------------|
| DataPoint Verified.               | (b) (4), (b) (6)                  | 19 Apr 2021 20:25:30 |
| User signature succeeded.         | Judith Martin (b) (4)<br>(b) (4)  | 28 Jan 2021 18:19:31 |
| User entered 'Seasonal Allergies' | Dominic Kramer (b) (4)<br>(b) (4) | 31 Aug 2020 13:59:39 |

**US3802074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:55:48**

[Dose per administration](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)                  | 19 Apr 2021 20:25:30 |
| User signature succeeded. | Judith Martin (b) (4)             | 28 Jan 2021 18:19:31 |
| User entered 'Unknown'    | (b) (4)<br>Dominic Kramer (b) (4) | 31 Aug 2020 13:59:39 |

**US3802074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:55:48**

[Dose unit](#)

| Audit                        | User                              | Time (GMT)           |
|------------------------------|-----------------------------------|----------------------|
| DataPoint Verified.          | (b) (4), (b) (6)                  | 19 Apr 2021 20:25:30 |
| User signature succeeded.    | Judith Martin (b) (4)<br>(b) (4)  | 28 Jan 2021 18:19:31 |
| User entered 'Other (OTHER)' | Dominic Kramer (b) (4)<br>(b) (4) | 31 Aug 2020 13:59:39 |

US3802074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:55:48

If dose unit is Other, specify

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)                  | 19 Apr 2021 20:25:30 |
| User signature succeeded. | Judith Martin (b) (4)             | 28 Jan 2021 18:19:31 |
| User entered 'Unknown'    | (b) (4)<br>Dominic Kramer (b) (4) | 31 Aug 2020 13:59:39 |

US3802074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:55:48

[Frequency](#)

| Audit                            | User                              | Time (GMT)           |
|----------------------------------|-----------------------------------|----------------------|
| DataPoint Verified.              | (b) (4), (b) (6)                  | 19 Apr 2021 20:25:30 |
| User signature succeeded.        | Judith Martin (b) (4)             | 28 Jan 2021 18:19:31 |
| User entered 'unknown (UNKNOWN)' | (b) (4)<br>Dominic Kramer (b) (4) | 31 Aug 2020 13:59:39 |

US3802074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:55:48

If frequency is Other, specify

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)                  | 19 Apr 2021 20:25:30 |
| User signature succeeded. | Judith Martin (b) (4)<br>(b) (4)  | 28 Jan 2021 18:19:31 |
| User entered empty.       | Dominic Kramer (b) (4)<br>(b) (4) | 31 Aug 2020 13:59:39 |

**US3802074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:55:48**

[Route of administration](#)

| Audit                      | User                              | Time (GMT)           |
|----------------------------|-----------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                  | 19 Apr 2021 20:25:30 |
| User signature succeeded.  | Judith Martin (b) (4)<br>(b) (4)  | 28 Jan 2021 18:19:31 |
| User entered 'Oral (ORAL)' | Dominic Kramer (b) (4)<br>(b) (4) | 31 Aug 2020 13:59:39 |



US3802074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:55:48

If route of administration is Other, specify

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)                  | 19 Apr 2021 20:25:30 |
| User signature succeeded. | Judith Martin (b) (4)<br>(b) (4)  | 28 Jan 2021 18:19:31 |
| User entered empty.       | Dominic Kramer (b) (4)<br>(b) (4) | 31 Aug 2020 13:59:39 |

**US3802074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:55:48**

[Start date \(dd MMM yyyy\)](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)                  | 19 Apr 2021 20:25:30 |
| User signature succeeded. | Judith Martin (b) (4)<br>(b) (4)  | 28 Jan 2021 18:19:31 |
| User entered empty.       | Dominic Kramer (b) (4)<br>(b) (4) | 31 Aug 2020 13:59:39 |

**US3802074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:55:48**

[Start date completely unknown](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)                  | 19 Apr 2021 20:25:30 |
| User signature succeeded. | Judith Martin (b) (4)<br>(b) (4)  | 28 Jan 2021 18:19:31 |
| User entered 'I'          | Dominic Kramer (b) (4)<br>(b) (4) | 31 Aug 2020 13:59:39 |

**US3802074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:55:48**

[Ongoing?](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)                  | 19 Apr 2021 20:25:30 |
| User signature succeeded. | Judith Martin (b) (4)<br>(b) (4)  | 28 Jan 2021 18:19:31 |
| User entered 'Yes (Y)'    | Dominic Kramer (b) (4)<br>(b) (4) | 31 Aug 2020 13:59:39 |

**US3802074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:55:48**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)                  | 19 Apr 2021 20:25:30 |
| User signature succeeded. | Judith Martin (b) (4)<br>(b) (4)  | 28 Jan 2021 18:19:31 |
| User entered empty.       | Dominic Kramer (b) (4)<br>(b) (4) | 31 Aug 2020 13:59:39 |

US3802074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:55:48

[Was this medication taken for solicited event?](#)

| Audit   | User                              | Time (GMT)           |
|---|-----------------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)                  | 19 Apr 2021 20:25:30 |
| User signature succeeded.   | Judith Martin (b) (4)             | 28 Jan 2021 18:19:31 |
| User closed query 'Per DM CLR: Was this medication taken for solicited event? = YES, however, the noted indication is not one of the listed solicited events per protocol. Please confirm and update as appropriate, otherwise clarify.' (Site from DM).              | (b) (4)<br>(b) (4), (b) (6)       | 27 Oct 2020 16:59:42 |
| Query 'Per DM CLR: Was this medication taken for solicited event? = YES, however, the noted indication is not one of the listed solicited events per protocol. Please confirm and update as appropriate, otherwise clarify.' answered with 'Updated ' (Site from DM). | Emily Carney (b) (4)<br>(b) (4)   | 21 Oct 2020 13:50:15 |
| User entered 'No (N)' reason for change: Data Entry Error   | Emily Carney (b) (4)<br>(b) (4)   | 21 Oct 2020 13:50:08 |
| User opened query 'Per DM CLR: Was this medication taken for solicited event? = YES, however, the noted indication is not one of the listed solicited events per protocol. Please confirm and update as appropriate, otherwise clarify.' (Site from DM).              | (b) (4), (b) (6)                  | 01 Oct 2020 14:36:55 |
| User entered 'Yes (Y)'  | Dominic Kramer (b) (4)<br>(b) (4) | 31 Aug 2020 13:59:39 |

**US3802074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:55:48**

[Separate Dosage Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 31 Aug 2020 13:59:39 |

**US3802074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:55:48**

[Interval Dosage Unit Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 31 Aug 2020 13:59:39 |



**US3802074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:55:48**

[Interval Dosage Definition \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 31 Aug 2020 13:59:39 |

US3802074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:55:48

Name of Medication

| Audit  | User                                       | Time (GMT)                                   |
|--|--|--|
| Data hard locked.  | (b) (4), (b) (6)                           | 30 Apr 2021 09:45:11                         |
| DataPoint Verified.  |  | 19 Apr 2021 20:25:30                         |
| User signature succeeded.  | Judith Martin (b) (4)                      | 28 Jan 2021 18:19:31                         |
| User coded data point as ATC:<br>MUSCULO-SKELETAL SYSTEM, ATC:<br>ANTIINFLAMMATORY AND ANTIRHEUMATIC<br>PRODUCTS, ATC: ANTIINFLAMMATORY AND<br>ANTIRHEUMATIC PRODUCTS,<br>NON-STERIODS, ATC: PROPIONIC ACID<br>DERIVATIVES, PRODUCT: IBUPROFEN,<br>PRODUCTSYNONYM: ADVIL [IBUPROFEN] -<br>version WHODrug-Global-B3\\202003. | (b) (4)<br>Coder Import (b) (4)<br>(b) (4) | 02 Dec 2020 13:57:08                         |
| 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)            | 02 Dec 2020 13:57:08                         |
| Data point term sent to Coder<br>Coding entries removed.   | System<br>Lalicia Roman (b) (4)<br>(b) (4) | 02 Dec 2020 13:55:56<br>02 Dec 2020 13:55:47 |
| User coded data point as ATC:<br>MUSCULO-SKELETAL SYSTEM, ATC:<br>ANTIINFLAMMATORY AND ANTIRHEUMATIC<br>PRODUCTS, ATC: ANTIINFLAMMATORY AND<br>ANTIRHEUMATIC PRODUCTS,<br>NON-STERIODS, ATC: PROPIONIC ACID<br>DERIVATIVES, PRODUCT: IBUPROFEN,<br>PRODUCTSYNONYM: ADVIL [IBUPROFEN] -<br>version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4)            | 05 Oct 2020 18:06:23                         |
| 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)            | 05 Oct 2020 18:06:23                         |
| Data point term sent to Coder<br>Coding entries removed.   | System<br>Lalicia Roman (b) (4)<br>(b) (4) | 05 Oct 2020 18:05:12<br>05 Oct 2020 18:04:41 |
| User entered 'ADVIL' reason for change: Data Entry<br>Error  | Lalicia Roman (b) (4)<br>(b) (4)           | 05 Oct 2020 18:04:41                         |

US3802074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:55:48

Name of Medication

| Audit  | User                             | Time (GMT)           |
|--|----------------------------------|----------------------|
| User coded data point as ATC:<br>MUSCULO-SKELETAL SYSTEM, ATC:<br>ANTIINFLAMMATORY AND ANTIRHEUMATIC<br>PRODUCTS, ATC: ANTIINFLAMMATORY AND<br>ANTIRHEUMATIC PRODUCTS,<br>NON-STEROIDS, ATC: PROPIONIC ACID<br>DERIVATIVES, PRODUCT: IBUPROFEN,<br>PRODUCTSYNONYM: ADVIL [IBUPROFEN] -<br>version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4)  | 17 Sep 2020 01:57:48 |
| User coded data point as Term Coded data point by<br>User: (b) (6) - version<br>WHODrug-Global-B3\\202003.   | Coder Import (b) (4)<br>(b) (4)  | 17 Sep 2020 01:57:48 |
| Data point term sent to Coder  | System                           | 16 Sep 2020 20:19:32 |
| Data point term sent to Coder  | System                           | 16 Sep 2020 20:18:31 |
| User entered 'advile'  | Jennifer Nagg (b) (4)<br>(b) (4) | 16 Sep 2020 20:18:05 |

**US3802074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:55:48**

[Prophylaxis](#)

| Audit                     | User  | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                            | 30 Apr 2021 09:45:11 |
| DataPoint Verified.       |   | 19 Apr 2021 20:25:30 |
| User signature succeeded. | Judith Martin (b) (4)                       | 28 Jan 2021 18:19:31 |
| User entered 'No (N)'     | (b) (4)<br>Jennifer Nagg (b) (4)<br>(b) (4) | 16 Sep 2020 20:18:05 |

US3802074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:55:48

[Indication](#)

| Audit   | User                             | Time (GMT)           |
|---|----------------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)                 | 30 Apr 2021 09:45:11 |
| DataPoint Verified.   |                                  | 19 Apr 2021 20:25:30 |
| User closed query 'Per DM CLR: Previous response noted. However, please confirm in query response that the recorded solicited event 'PAIN AT INJECTION SITE' doesn't meet any of the AE reporting criteria mentioned in previous query. Thank you<br>' (Site from DM).  |                                  | 08 Feb 2021 15:46:56 |
| Query 'Per DM CLR: Previous response noted. However, please confirm in query response that the recorded solicited event 'PAIN AT INJECTION SITE' doesn't meet any of the AE reporting criteria mentioned in previous query. Thank you<br>' answered with 'This does not meet AE reporting criteria' (Site from DM).   | Emily Carney (b) (4)<br>(b) (4)  | 04 Feb 2021 19:59:03 |
| User opened query 'Per DM CLR: Previous response noted. However, please confirm in query response that the recorded solicited event 'PAIN AT INJECTION SITE' doesn't meet any of the AE reporting criteria mentioned in previous query. Thank you<br>' (Site from DM).  | (b) (4), (b) (6)                 | 30 Jan 2021 11:49:04 |
| User signature succeeded.   | Judith Martin (b) (4)<br>(b) (4) | 28 Jan 2021 18:19:31 |
| User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the PAIN AT INJECTION SITE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria:results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of PAIN AT INJECTION SITE did not meet the AE reporting criteria.' (Site from DM). | (b) (4), (b) (6)                 | 19 Jan 2021 17:57:33 |

US3802074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:55:48

[Indication](#)

| Audit  | User                  | Time (GMT)           |
|--|-----------------------|----------------------|
| Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the PAIN AT INJECTION SITE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria:results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of PAIN AT INJECTION SITE did not meet the AE reporting criteria.' answered with 'medication take for symptoms recorded in diary' (Site from DM). | Jamie Fries (b) (4)   | 15 Jan 2021 19:04:38 |
| User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the PAIN AT INJECTION SITE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria:results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of PAIN AT INJECTION SITE did not meet the AE reporting criteria.' (Site from DM).  | (b) (4), (b) (6)      | 04 Jan 2021 07:08:03 |
| User entered 'Pain at injection site' reason for change: Data Entry Error  | Lalicia Roman (b) (4) | 02 Dec 2020 13:55:47 |
| User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the ARM PAIN is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of ARM PAIN did not meet the AE reporting criteria.' (Site from DM).   | (b) (4), (b) (6)      | 17 Nov 2020 05:07:09 |

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EAB) (1725)

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US3802074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:55:48

Indication

| Audit   | User                    | Time (GMT)           |
|---|-------------------------|----------------------|
| Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the ARM PAIN is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of ARM PAIN did not meet the AE reporting criteria.' answered with 'Captured in Diary. No AE to report' (Site from DM). | Emily Dougherty (b) (4) | 12 Nov 2020 21:13:45 |
| User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the ARM PAIN is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of ARM PAIN did not meet the AE reporting criteria.' (Site from DM).  | (b) (4), (b) (6)        | 30 Oct 2020 01:37:44 |
| User entered 'arm pain'   | Jennifer Nagg (b) (4)   | 16 Sep 2020 20:18:05 |

US3802074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:55:48

[Dose per administration](#)

| Audit  | User                  | Time (GMT)           |
|--|-----------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)      | 30 Apr 2021 09:45:11 |
| DataPoint Verified.  |                       | 19 Apr 2021 20:25:30 |
| User signature succeeded.  | Judith Martin (b) (4) | 28 Jan 2021 18:19:31 |
| User closed query 'Data is required. Please complete.' (Site from System).             | (b) (4)               |                      |
|  | System                | 16 Sep 2020 20:18:40 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System                | 16 Sep 2020 20:18:40 |
| User entered '400' reason for change: Data Entry Error                                 | Jennifer Nagg (b) (4) | 16 Sep 2020 20:18:40 |
|  | (b) (4)               |                      |
| User opened query 'Data is required. Please complete.' (Site from System).             | System                | 16 Sep 2020 20:18:05 |
| User entered empty.  | Jennifer Nagg (b) (4) | 16 Sep 2020 20:18:05 |
|  | (b) (4)               |                      |



US3802074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:55:48

[Dose unit](#)

| Audit  | User                  | Time (GMT)           |
|--|-----------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)      | 30 Apr 2021 09:45:11 |
| DataPoint Verified.  |                       | 19 Apr 2021 20:25:30 |
| User signature succeeded.  | Judith Martin (b) (4) | 28 Jan 2021 18:19:31 |
| User closed query 'Data is required. Please complete.' (Site from System).             | (b) (4)               |                      |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System                | 16 Sep 2020 20:18:40 |
| User entered 'mg (mg)' reason for change: Data Entry Error                             | System                | 16 Sep 2020 20:18:40 |
| User opened query 'Data is required. Please complete.' (Site from System).             | Jennifer Nagg (b) (4) | 16 Sep 2020 20:18:05 |
| User entered empty.  | Jennifer Nagg (b) (4) | 16 Sep 2020 20:18:05 |

**US3802074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:55:48**

[If dose unit is Other, specify](#)

| Audit                     | User  | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                            | 30 Apr 2021 09:45:11 |
| DataPoint Verified.       |   | 19 Apr 2021 20:25:30 |
| User signature succeeded. | Judith Martin (b) (4)                       | 28 Jan 2021 18:19:31 |
| User entered empty.       | (b) (4)<br>Jennifer Nagg (b) (4)<br>(b) (4) | 16 Sep 2020 20:18:05 |

US3802074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:55:48

[Frequency](#)

| Audit  | User                  | Time (GMT)           |
|--|-----------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)      | 30 Apr 2021 09:45:11 |
| DataPoint Verified.  |                       | 19 Apr 2021 20:25:30 |
| User signature succeeded.  | Judith Martin (b) (4) | 28 Jan 2021 18:19:31 |
| User closed query 'Data is required. Please complete.' (Site from System).             | (b) (4)               |                      |
|  | System                | 16 Sep 2020 20:18:40 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System                | 16 Sep 2020 20:18:40 |
| User entered 'as needed (PRN)' reason for change:                                      | Jennifer Nagg (b) (4) | 16 Sep 2020 20:18:40 |
| Data Entry Error   | (b) (4)               |                      |
| User opened query 'Data is required. Please complete.' (Site from System).             | System                | 16 Sep 2020 20:18:05 |
| User entered empty.  | Jennifer Nagg (b) (4) | 16 Sep 2020 20:18:05 |
|  | (b) (4)               |                      |

**US3802074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:55:48**

[If frequency is Other, specify](#)

| Audit                     | User  | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                            | 30 Apr 2021 09:45:11 |
| DataPoint Verified.       |   | 19 Apr 2021 20:25:30 |
| User signature succeeded. | Judith Martin (b) (4)                       | 28 Jan 2021 18:19:31 |
| User entered empty.       | (b) (4)<br>Jennifer Nagg (b) (4)<br>(b) (4) | 16 Sep 2020 20:18:05 |

US3802074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:55:48

[Route of administration](#)

| Audit  | User                  | Time (GMT)           |
|--|-----------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)      | 30 Apr 2021 09:45:11 |
| DataPoint Verified.  |                       | 19 Apr 2021 20:25:30 |
| User signature succeeded.  | Judith Martin (b) (4) | 28 Jan 2021 18:19:31 |
| User closed query 'Data is required. Please complete.' (Site from System).             | (b) (4)               |                      |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System                | 16 Sep 2020 20:18:40 |
| User entered 'Oral (ORAL)' reason for change: Data Entry Error                         | System                | 16 Sep 2020 20:18:40 |
| User opened query 'Data is required. Please complete.' (Site from System).             | Jennifer Nagg (b) (4) | 16 Sep 2020 20:18:40 |
| User entered empty.  | (b) (4)               | 16 Sep 2020 20:18:05 |
|  | Jennifer Nagg (b) (4) | 16 Sep 2020 20:18:05 |
|  | (b) (4)               |                      |

**US3802074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:55:48**

[If route of administration is Other, specify](#)

| Audit                     | User  | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                            | 30 Apr 2021 09:45:11 |
| DataPoint Verified.       |   | 19 Apr 2021 20:25:30 |
| User signature succeeded. | Judith Martin (b) (4)                       | 28 Jan 2021 18:19:31 |
| User entered empty.       | (b) (4)<br>Jennifer Nagg (b) (4)<br>(b) (4) | 16 Sep 2020 20:18:05 |

**US3802074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:55:48**

[Start date \(dd MMM yyyy\)](#)

| Audit                     | User  | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                            | 30 Apr 2021 09:45:11 |
| DataPoint Verified.       |   | 19 Apr 2021 20:25:30 |
| User signature succeeded. | Judith Martin (b) (4)                       | 28 Jan 2021 18:19:31 |
| User entered '1 Sep 2020' | (b) (4)<br>Jennifer Nagg (b) (4)<br>(b) (4) | 16 Sep 2020 20:18:05 |

**US3802074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:55:48**

[Start date completely unknown](#)

| Audit                     | User  | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                            | 30 Apr 2021 09:45:11 |
| DataPoint Verified.       |   | 19 Apr 2021 20:25:30 |
| User signature succeeded. | Judith Martin (b) (4)                       | 28 Jan 2021 18:19:31 |
| User entered '0'          | (b) (4)<br>Jennifer Nagg (b) (4)<br>(b) (4) | 16 Sep 2020 20:18:05 |



US3802074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:55:48

[Ongoing?](#)

| Audit   | User                    | Time (GMT)           |
|---|-------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)        | 30 Apr 2021 09:45:11 |
| DataPoint Verified.                                       |                         | 19 Apr 2021 20:25:30 |
| User signature succeeded.                                 | Judith Martin (b) (4)   | 28 Jan 2021 18:19:31 |
| User entered 'No (N)' reason for change: Data Entry Error | (b) (4)                 |                      |
|   | Emily Dougherty (b) (4) | 12 Nov 2020 21:17:29 |
| User entered 'Yes (Y)'                                    | (b) (4)                 |                      |
|   | Jennifer Nagg (b) (4)   | 16 Sep 2020 20:18:05 |
|   | (b) (4)                 |                      |

US3802074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:55:48

If not Ongoing, End date (*dd MMM yyyy*)

| Audit  | User                    | Time (GMT)           |
|--|-------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)        | 30 Apr 2021 09:45:11 |
| DataPoint Verified.  |                         | 19 Apr 2021 20:25:30 |
| User signature succeeded.                                      | Judith Martin (b) (4)   | 28 Jan 2021 18:19:31 |
| User entered '06 Sep 2020' reason for change: Data Entry Error | (b) (4)                 |                      |
|  | Emily Dougherty (b) (4) | 12 Nov 2020 21:17:29 |
| User entered empty.  | (b) (4)                 |                      |
|  | Jennifer Nagg (b) (4)   | 16 Sep 2020 20:18:05 |
|  | (b) (4)                 |                      |

US3802074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:55:48

[Was this medication taken for solicited event?](#)

| Audit   | User                             | Time (GMT)           |
|---|----------------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)                 | 30 Apr 2021 09:45:11 |
| DataPoint Verified.   |                                  | 19 Apr 2021 20:25:30 |
| User signature succeeded.   | Judith Martin (b) (4)            | 28 Jan 2021 18:19:31 |
| User closed query 'Per DM CLR: Please note, 'Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body). Please review and update eCRF. Otherwise clarify.' (Site from DM).   | (b) (4)<br>(b) (4), (b) (6)      | 04 Dec 2020 11:37:58 |
| Query 'Per DM CLR: Please note, 'Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body). Please review and update eCRF. Otherwise clarify.' answered with 'Participant indicated in the their diary that they had pain at the injection site. They reported the medication and the dose, they took at the time of the safety call.' (Site from DM). | Lalicia Roman (b) (4)<br>(b) (4) | 02 Dec 2020 13:56:37 |
| User opened query 'Per DM CLR: Please note, 'Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body). Please review and update eCRF. Otherwise clarify.' (Site from DM).   | (b) (4), (b) (6)                 | 26 Nov 2020 20:40:55 |
| User entered 'Yes (Y)'  | Jennifer Nagg (b) (4)<br>(b) (4) | 16 Sep 2020 20:18:05 |

**US3802074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:55:48**

[Separate Dosage Number \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 30 Apr 2021 09:45:11 |
| User entered empty. | System           | 16 Sep 2020 20:18:05 |

**US3802074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:55:48**

[Interval Dosage Unit Number \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 30 Apr 2021 09:45:11 |
| User entered empty. | System           | 16 Sep 2020 20:18:05 |

**US3802074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:55:48**

[Interval Dosage Definition \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 30 Apr 2021 09:45:11 |
| User entered empty. | System           | 16 Sep 2020 20:18:05 |

US3802074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:55:48

Name of Medication

| Audit   | User                            | Time (GMT)           |
|---|---------------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)                | 30 Apr 2021 09:45:16 |
| DataPoint Verified.   |                                 | 19 Apr 2021 20:25:30 |
| User closed query 'Per DM CLR: Please review if this medication was added because the patient's medical history of SEASONAL ALLERGIES worsened. If yes, please review if an AE reflecting worsening of corresponding MH condition should be recorded. Update all applicable eCRFs if appropriate. ' (Site from DM).   |                                 | 31 Mar 2021 07:41:58 |
| Query 'Per DM CLR: Please review if this medication was added because the patient's medical history of SEASONAL ALLERGIES worsened. If yes, please review if an AE reflecting worsening of corresponding MH condition should be recorded. Update all applicable eCRFs if appropriate. ' answered with 'No this is not worsening rather this is seasonal allergies meaning it happens during certain times of the year. Therefore this doesn't meet AE reporting criteria. ' (Site from DM). | Emily Carney (b) (4)<br>(b) (4) | 30 Mar 2021 13:56:12 |
| User opened query 'Per DM CLR: Please review if this medication was added because the patient's medical history of SEASONAL ALLERGIES worsened. If yes, please review if an AE reflecting worsening of corresponding MH condition should be recorded. Update all applicable eCRFs if appropriate. ' (Site from DM).   | (b) (4), (b) (6)                | 30 Mar 2021 09:32:12 |
| User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: OTHER ANTIHISTAMINES FOR SYSTEMIC USE, PRODUCT: LORATADINE, PRODUCTSYNONYM: CLARITIN [LORATADINE] - version WHODrug-Global-B3\\202003.   | Coder Import (b) (4)<br>(b) (4) | 13 Feb 2021 00:31:53 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.  | Coder Import (b) (4)<br>(b) (4) | 13 Feb 2021 00:31:53 |
| Data point term sent to Coder   | System                          | 11 Feb 2021 21:03:42 |

US3802074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:55:48

[Name of Medication](#)

| Audit   | User                  | Time (GMT)           |
|---|-----------------------|----------------------|
| Coding entries removed.   | Lalicia Roman (b) (4) | 11 Feb 2021 21:03:14 |
|   | (b) (4)               |                      |
| User signature succeeded.   | Judith Martin (b) (4) | 28 Jan 2021 18:19:31 |
|   | (b) (4)               |                      |
| User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: OTHER ANTIHISTAMINES FOR SYSTEMIC USE, PRODUCT: LORATADINE, PRODUCTSYNONYM: CLARITIN [LORATADINE] - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)  | 18 Nov 2020 23:13:50 |
|   | (b) (4)               |                      |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.  | Coder Import (b) (4)  | 18 Nov 2020 23:13:50 |
|   | (b) (4)               |                      |
| Data point term sent to Coder   | System                | 18 Nov 2020 18:05:13 |
| User entered 'Claritin'   | Emily Carney (b) (4)  | 18 Nov 2020 18:05:06 |
|   | (b) (4)               |                      |



**US3802074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:55:48**

[Prophylaxis](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 30 Apr 2021 09:45:16 |
| DataPoint Verified.       |                       | 19 Apr 2021 20:25:30 |
| User signature succeeded. | Judith Martin (b) (4) | 28 Jan 2021 18:19:31 |
| User entered 'No (N)'     | (b) (4)               |                      |
|                           | Emily Carney (b) (4)  | 18 Nov 2020 18:05:06 |
|                           | (b) (4)               |                      |

US3802074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:55:48

[Indication](#)

| Audit  | User                             | Time (GMT)           |
|--|----------------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)                 | 30 Apr 2021 09:45:16 |
| DataPoint Verified.  |                                  | 19 Apr 2021 20:25:30 |
| User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria:results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE did not meet the AE reporting criteria. ' (Site from DM).   |                                  | 16 Feb 2021 11:12:34 |
| User signature succeeded.  | Judith Martin (b) (4)            | 13 Feb 2021 12:27:55 |
| Signature has been broken.   | (b) (4)<br>Lalicia Roman (b) (4) | 11 Feb 2021 21:03:14 |
| User entered 'SINUS HEADACHE related to seasonal allergies' reason for change: Data Entry Error  | (b) (4)<br>Lalicia Roman (b) (4) | 11 Feb 2021 21:03:14 |
| Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria:results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE did not meet the AE reporting criteria. ' answered with 'There is no AE to match because the participant has a medical history of seasonal allergies and on occasion he gets sinus headaches which he treats with claritin. He reported this at the time of his enrollment. ' (Site from DM). | Lalicia Roman (b) (4)<br>(b) (4) | 11 Feb 2021 21:02:51 |

US3802074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:55:48

[Indication](#)

| Audit   | User                            | Time (GMT)           |
|---|---------------------------------|----------------------|
| User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria:results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE did not meet the AE reporting criteria.<br />' (Site from DM). | (b) (4), (b) (6)                | 30 Jan 2021 11:49:55 |
| User signature succeeded.   | Judith Martin (b) (4)           | 28 Jan 2021 18:19:31 |
| User closed query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' (Site from DM).   | (b) (4)<br>(b) (4), (b) (6)     | 20 Jan 2021 19:01:53 |
| Query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' answered with 'This medication is used for this as well. helps to decrease nasal swelling and congestion which in turn will help eliminate headache ' (Site from DM).   | Jamie Fries (b) (4)<br>(b) (4)  | 19 Jan 2021 16:44:56 |
| User opened query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' (Site from DM).   | (b) (4), (b) (6)                | 04 Jan 2021 07:08:13 |
| User entered 'Sinus headache'   | Emily Carney (b) (4)<br>(b) (4) | 18 Nov 2020 18:05:06 |

US3802074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:55:48

[Dose per administration](#)

| Audit  | User                  | Time (GMT)           |
|--|-----------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)      | 30 Apr 2021 09:45:16 |
| DataPoint Verified.  |                       | 19 Apr 2021 20:25:30 |
| User closed query 'Per CDM: Kindly review and update the Dose per administration as appropriate (eg: 5mg, 10mg or 20mg). Thankyou.' (Site from DM).  |                       | 01 Mar 2021 16:15:18 |
| Query 'Per CDM: Kindly review and update the Dose per administration as appropriate (eg: 5mg, 10mg or 20mg). Thankyou.' answered with 'Patient contacted and stated dosage was unknown.' (Site from DM). | Lisa Vavro (b) (4)    | 23 Feb 2021 20:37:48 |
| User opened query 'Per CDM: Kindly review and update the Dose per administration as appropriate (eg: 5mg, 10mg or 20mg). Thankyou.' (Site from DM).  | (b) (4)               |                      |
| User signature succeeded.  | (b) (4), (b) (6)      | 22 Feb 2021 14:34:13 |
| User entered 'Unk'   | Judith Martin (b) (4) | 28 Jan 2021 18:19:31 |
|  | (b) (4)               |                      |
|  | Emily Carney (b) (4)  | 18 Nov 2020 18:05:06 |
|  | (b) (4)               |                      |

**US3802074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:55:48**

[Dose unit](#)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 30 Apr 2021 09:45:16 |
| DataPoint Verified.       |  | 19 Apr 2021 20:25:30 |
| User signature succeeded. | Judith Martin (b) (4)                      | 28 Jan 2021 18:19:31 |
| User entered 'mg (mg)'    | (b) (4)<br>Emily Carney (b) (4)<br>(b) (4) | 18 Nov 2020 18:05:06 |

**US3802074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:55:48**

[If dose unit is Other, specify](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 30 Apr 2021 09:45:16 |
| DataPoint Verified.       |                       | 19 Apr 2021 20:25:30 |
| User signature succeeded. | Judith Martin (b) (4) | 28 Jan 2021 18:19:31 |
| User entered empty.       | (b) (4)               |                      |
|                           | Emily Carney (b) (4)  | 18 Nov 2020 18:05:06 |
|                           | (b) (4)               |                      |

**US3802074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:55:48**

[Frequency](#)

| Audit                          | User                  | Time (GMT)           |
|--------------------------------|-----------------------|----------------------|
| Data hard locked.              | (b) (4), (b) (6)      | 30 Apr 2021 09:45:16 |
| DataPoint Verified.            |                       | 19 Apr 2021 20:25:30 |
| User signature succeeded.      | Judith Martin (b) (4) | 28 Jan 2021 18:19:31 |
| User entered 'as needed (PRN)' | (b) (4)               |                      |
|                                | Emily Carney (b) (4)  | 18 Nov 2020 18:05:06 |
|                                | (b) (4)               |                      |

US3802074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:55:48

If frequency is Other, specify

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 30 Apr 2021 09:45:16 |
| DataPoint Verified.       |                       | 19 Apr 2021 20:25:30 |
| User signature succeeded. | Judith Martin (b) (4) | 28 Jan 2021 18:19:31 |
| User entered empty.       | (b) (4)               |                      |
|                           | Emily Carney (b) (4)  | 18 Nov 2020 18:05:06 |
|                           | (b) (4)               |                      |



**US3802074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:55:48**

[Route of administration](#)

| Audit                      | User                                       | Time (GMT)           |
|----------------------------|--|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                           | 30 Apr 2021 09:45:16 |
| DataPoint Verified.        |  | 19 Apr 2021 20:25:30 |
| User signature succeeded.  | Judith Martin (b) (4)                      | 28 Jan 2021 18:19:31 |
| User entered 'Oral (ORAL)' | (b) (4)<br>Emily Carney (b) (4)<br>(b) (4) | 18 Nov 2020 18:05:06 |

**US3802074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:55:48**

[If route of administration is Other, specify](#)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 30 Apr 2021 09:45:16 |
| DataPoint Verified.       |  | 19 Apr 2021 20:25:30 |
| User signature succeeded. | Judith Martin (b) (4)                      | 28 Jan 2021 18:19:31 |
| User entered empty.       | (b) (4)<br>Emily Carney (b) (4)<br>(b) (4) | 18 Nov 2020 18:05:06 |

US3802074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:55:48

Start date (dd MMM yyyy)

| Audit   | User                             | Time (GMT)           |
|---|----------------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)                 | 30 Apr 2021 09:45:16 |
| DataPoint Verified.   |                                  | 19 Apr 2021 20:25:30 |
| User closed query 'Per DM CLR: Please review Start date of this medication as this is before the occurrence of HEADACHE which started 6SEP2020 per Diary. Either update CM start date or confirm in query response that CM was given during this recorded date<br>' (Site from DM).   |                                  | 16 Feb 2021 11:12:49 |
| Query 'Per DM CLR: Please review Start date of this medication as this is before the occurrence of HEADACHE which started 6SEP2020 per Diary. Either update CM start date or confirm in query response that CM was given during this recorded date<br>' answered with 'participant suffers from seasonal allergies and takes claritin for sinus headaches. This is the date he reported at the time of his enrollment. '<br>(Site from DM). | Lalicia Roman (b) (4)<br>(b) (4) | 11 Feb 2021 21:05:28 |
| User opened query 'Per DM CLR: Please review Start date of this medication as this is before the occurrence of HEADACHE which started 6SEP2020 per Diary. Either update CM start date or confirm in query response that CM was given during this recorded date<br>' (Site from DM).   | (b) (4), (b) (6)                 | 30 Jan 2021 11:52:59 |
| User signature succeeded.   | Judith Martin (b) (4)<br>(b) (4) | 28 Jan 2021 18:19:31 |
| User entered '1 Sep 2020'   | Emily Carney (b) (4)<br>(b) (4)  | 18 Nov 2020 18:05:06 |

**US3802074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:55:48**

[Start date completely unknown](#)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 30 Apr 2021 09:45:16 |
| DataPoint Verified.       |  | 19 Apr 2021 20:25:30 |
| User signature succeeded. | Judith Martin (b) (4)                      | 28 Jan 2021 18:19:31 |
| User entered '0'          | (b) (4)<br>Emily Carney (b) (4)<br>(b) (4) | 18 Nov 2020 18:05:06 |

**US3802074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:55:48**

[Ongoing?](#)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 30 Apr 2021 09:45:16 |
| DataPoint Verified.       |  | 19 Apr 2021 20:25:30 |
| User signature succeeded. | Judith Martin (b) (4)                      | 28 Jan 2021 18:19:31 |
| User entered 'No (N)'     | (b) (4)<br>Emily Carney (b) (4)<br>(b) (4) | 18 Nov 2020 18:05:06 |

**US3802074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:55:48**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 30 Apr 2021 09:45:16 |
| DataPoint Verified.       |  | 19 Apr 2021 20:25:30 |
| User signature succeeded. | Judith Martin (b) (4)                      | 28 Jan 2021 18:19:31 |
| User entered '6 Sep 2020' | (b) (4)<br>Emily Carney (b) (4)<br>(b) (4) | 18 Nov 2020 18:05:06 |

US3802074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:55:48

[Was this medication taken for solicited event?](#)

| Audit   | User                            | Time (GMT)           |
|---|---------------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)                | 30 Apr 2021 09:45:16 |
| DataPoint Verified.   |                                 | 19 Apr 2021 20:25:30 |
| User signature succeeded.   | Judith Martin (b) (4)           | 12 Mar 2021 14:51:19 |
| User closed query 'Per DM CLR: Please note, 'Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body). Please review and update eCRF. Otherwise clarify.<br>' (Site from DM).             | (b) (4)<br>(b) (4), (b) (6)     | 11 Mar 2021 12:03:38 |
| Query 'Per DM CLR: Please note, 'Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body). Please review and update eCRF. Otherwise clarify.<br>' answered with 'updated' (Site from DM). | Emily Carney (b) (4)<br>(b) (4) | 10 Mar 2021 21:05:42 |
| Signature has been broken.  | Emily Carney (b) (4)<br>(b) (4) | 10 Mar 2021 21:05:14 |
| User entered 'No (N)' reason for change: Data Entry Error   | Emily Carney (b) (4)<br>(b) (4) | 10 Mar 2021 21:05:14 |
| User opened query 'Per DM CLR: Please note, 'Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body). Please review and update eCRF. Otherwise clarify.<br />' (Site from DM).           | (b) (4), (b) (6)                | 10 Mar 2021 08:54:03 |

US3802074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:55:48

Was this medication taken for solicited event?

| Audit   | User                             | Time (GMT)           |
|---|----------------------------------|----------------------|
| Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the SINUS HEADACHE RELATED TO SEASONAL ALLERGIES is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that this solicited adverse reaction did not meet the AE reporting criteria.<br />' canceled (Site from DM). | (b) (4), (b) (6)                 | 10 Mar 2021 08:53:25 |
| User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the SINUS HEADACHE RELATED TO SEASONAL ALLERGIES is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that this solicited adverse reaction did not meet the AE reporting criteria. ' (Site from DM).   | (b) (4), (b) (6)                 | 10 Mar 2021 08:53:14 |
| User signature succeeded.   | Judith Martin (b) (4)<br>(b) (4) | 28 Jan 2021 18:19:31 |
| User entered 'Yes (Y)'  | Emily Carney (b) (4)<br>(b) (4)  | 18 Nov 2020 18:05:06 |



**US3802074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:55:48**

[Separate Dosage Number \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 30 Apr 2021 09:45:16 |
| User entered empty. | System           | 18 Nov 2020 18:05:06 |

**US3802074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:55:48**

[Interval Dosage Unit Number \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 30 Apr 2021 09:45:16 |
| User entered empty. | System           | 18 Nov 2020 18:05:06 |

**US3802074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:55:48**

[Interval Dosage Definition \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 30 Apr 2021 09:45:16 |
| User entered empty. | System           | 18 Nov 2020 18:05:06 |

US3802074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:55:48

[Name of Medication](#)

| Audit  | User                             | Time (GMT)           |
|--|----------------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)                 | 30 Apr 2021 09:45:22 |
| DataPoint Verified.  |                                  | 19 Apr 2021 20:25:30 |
| User coded data point as ATC:<br>MUSCULO-SKELETAL SYSTEM, ATC:<br>ANTIINFLAMMATORY AND ANTIRHEUMATIC<br>PRODUCTS, ATC: ANTIINFLAMMATORY AND<br>ANTIRHEUMATIC PRODUCTS,<br>NON-STEROIDS, ATC: PROPIONIC ACID<br>DERIVATIVES, PRODUCT: IBUPROFEN,<br>PRODUCTSYNONYM: ADVIL [IBUPROFEN] -<br>version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4)  | 11 Feb 2021 23:00:57 |
| 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)  | 11 Feb 2021 23:00:57 |
| Data point term sent to Coder  | System                           | 11 Feb 2021 21:08:48 |
| Coding entries removed.  | Lalicia Roman (b) (4)<br>(b) (4) | 11 Feb 2021 21:08:19 |
| User signature succeeded.  | Judith Martin (b) (4)<br>(b) (4) | 28 Jan 2021 18:19:31 |
| User coded data point as ATC:<br>MUSCULO-SKELETAL SYSTEM, ATC:<br>ANTIINFLAMMATORY AND ANTIRHEUMATIC<br>PRODUCTS, ATC: ANTIINFLAMMATORY AND<br>ANTIRHEUMATIC PRODUCTS,<br>NON-STEROIDS, ATC: PROPIONIC ACID<br>DERIVATIVES, PRODUCT: IBUPROFEN,<br>PRODUCTSYNONYM: ADVIL [IBUPROFEN] -<br>version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4)  | 18 Nov 2020 22:57:49 |
| 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)  | 18 Nov 2020 22:57:49 |
| Data point term sent to Coder  | System                           | 18 Nov 2020 18:09:15 |
| User entered 'Advil'   | Emily Carney (b) (4)<br>(b) (4)  | 18 Nov 2020 18:08:55 |

**US3802074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:55:48**

[Prophylaxis](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 30 Apr 2021 09:45:22 |
| DataPoint Verified.       |                       | 19 Apr 2021 20:25:30 |
| User signature succeeded. | Judith Martin (b) (4) | 28 Jan 2021 18:19:31 |
| User entered 'No (N)'     | (b) (4)               |                      |
|                           | Emily Carney (b) (4)  | 18 Nov 2020 18:08:55 |
|                           | (b) (4)               |                      |

US3802074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:55:48

[Indication](#)

| Audit   | User                             | Time (GMT)           |
|---|----------------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)                 | 30 Apr 2021 09:45:22 |
| DataPoint Verified.   |                                  | 19 Apr 2021 20:25:30 |
| User signature succeeded.   | Judith Martin (b) (4)            | 13 Feb 2021 12:27:55 |
| Signature has been broken.  | (b) (4)<br>Lalicia Roman (b) (4) | 11 Feb 2021 21:08:19 |
| User entered 'ARM PAIN AT INJECTION SITE Headache' reason for change: Data Entry Error  | (b) (4)<br>Lalicia Roman (b) (4) | 11 Feb 2021 21:08:19 |
| User closed query 'Per DM CLR: Previous response noted. However, please confirm in query response that the recorded solicited event 'ARM PAIN AT INJECTION SITE' doesn't meet any of the AE reporting criteria mentioned in previous query. Thank you | (b) (4), (b) (6)                 | 08 Feb 2021 15:46:05 |
| ' (Site from DM).   |                                  |                      |
| Query 'Per DM CLR: Previous response noted. However, please confirm in query response that the recorded solicited event 'ARM PAIN AT INJECTION SITE' doesn't meet any of the AE reporting criteria mentioned in previous query. Thank you             | Emily Carney (b) (4)<br>(b) (4)  | 04 Feb 2021 20:00:08 |
| ' answered with 'This does not meet AE reporting criteria' (Site from DM).  |                                  |                      |
| User opened query 'Per DM CLR: Previous response noted. However, please confirm in query response that the recorded solicited event 'ARM PAIN AT INJECTION SITE' doesn't meet any of the AE reporting criteria mentioned in previous query. Thank you | (b) (4), (b) (6)                 | 30 Jan 2021 11:54:21 |
| ' (Site from DM).   |                                  |                      |
| User signature succeeded.   | Judith Martin (b) (4)<br>(b) (4) | 28 Jan 2021 18:19:31 |

US3802074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:55:48

[Indication](#)

| Audit  | User                            | Time (GMT)           |
|--|---------------------------------|----------------------|
| User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the ARM PAIN AT INJECTION SITE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria:results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of ARM PAIN AT INJECTION SITE did not meet the AE reporting criteria.' (Site from DM).  | (b) (4), (b) (6)                | 22 Jan 2021 15:07:42 |
| Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the ARM PAIN AT INJECTION SITE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria:results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of ARM PAIN AT INJECTION SITE did not meet the AE reporting criteria.' answered with 'Not an AE because it was captured on the diary. Participant reported taking medication for injection site pain on Sep 29 and verbally reported the other days during their safety call. ' (Site from DM). | Emily Carney (b) (4)<br>(b) (4) | 19 Jan 2021 17:46:18 |

US3802074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:55:48

[Indication](#)

| Audit   | User                            | Time (GMT)           |
|---|---------------------------------|----------------------|
| User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the ARM PAIN AT INJECTION SITE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria:results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of ARM PAIN AT INJECTION SITE did not meet the AE reporting criteria.' (Site from DM). | (b) (4), (b) (6)                | 04 Jan 2021 07:08:28 |
| User entered 'Arm pain at injection site'   | Emily Carney (b) (4)<br>(b) (4) | 18 Nov 2020 18:08:55 |



**US3802074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:55:48**

[Dose per administration](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 30 Apr 2021 09:45:22 |
| DataPoint Verified.       |                       | 19 Apr 2021 20:25:30 |
| User signature succeeded. | Judith Martin (b) (4) | 28 Jan 2021 18:19:31 |
| User entered '400'        | (b) (4)               |                      |
|                           | Emily Carney (b) (4)  | 18 Nov 2020 18:08:55 |
|                           | (b) (4)               |                      |

**US3802074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:55:48**

[Dose unit](#)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 30 Apr 2021 09:45:22 |
| DataPoint Verified.       |  | 19 Apr 2021 20:25:30 |
| User signature succeeded. | Judith Martin (b) (4)                      | 28 Jan 2021 18:19:31 |
| User entered 'mg (mg)'    | (b) (4)<br>Emily Carney (b) (4)<br>(b) (4) | 18 Nov 2020 18:08:55 |

**US3802074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:55:48**

[If dose unit is Other, specify](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 30 Apr 2021 09:45:22 |
| DataPoint Verified.       |                       | 19 Apr 2021 20:25:30 |
| User signature succeeded. | Judith Martin (b) (4) | 28 Jan 2021 18:19:31 |
| User entered empty.       | (b) (4)               |                      |
|                           | Emily Carney (b) (4)  | 18 Nov 2020 18:08:55 |
|                           | (b) (4)               |                      |

**US3802074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:55:48**

[Frequency](#)

| Audit                          | User                  | Time (GMT)           |
|--------------------------------|-----------------------|----------------------|
| Data hard locked.              | (b) (4), (b) (6)      | 30 Apr 2021 09:45:22 |
| DataPoint Verified.            |                       | 19 Apr 2021 20:25:30 |
| User signature succeeded.      | Judith Martin (b) (4) | 28 Jan 2021 18:19:31 |
| User entered 'as needed (PRN)' | (b) (4)               |                      |
|                                | Emily Carney (b) (4)  | 18 Nov 2020 18:08:55 |
|                                | (b) (4)               |                      |

**US3802074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:55:48**

[If frequency is Other, specify](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 30 Apr 2021 09:45:22 |
| DataPoint Verified.       |                       | 19 Apr 2021 20:25:30 |
| User signature succeeded. | Judith Martin (b) (4) | 28 Jan 2021 18:19:31 |
| User entered empty.       | (b) (4)               |                      |
|                           | Emily Carney (b) (4)  | 18 Nov 2020 18:08:55 |
|                           | (b) (4)               |                      |

**US3802074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:55:48**

[Route of administration](#)

| Audit                      | User                                       | Time (GMT)           |
|----------------------------|--|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                           | 30 Apr 2021 09:45:22 |
| DataPoint Verified.        |  | 19 Apr 2021 20:25:30 |
| User signature succeeded.  | Judith Martin (b) (4)                      | 28 Jan 2021 18:19:31 |
| User entered 'Oral (ORAL)' | (b) (4)<br>Emily Carney (b) (4)<br>(b) (4) | 18 Nov 2020 18:08:55 |

**US3802074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:55:48**

[If route of administration is Other, specify](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 30 Apr 2021 09:45:22 |
| DataPoint Verified.       |                       | 19 Apr 2021 20:25:30 |
| User signature succeeded. | Judith Martin (b) (4) | 28 Jan 2021 18:19:31 |
| User entered empty.       | (b) (4)               |                      |
|                           | Emily Carney (b) (4)  | 18 Nov 2020 18:08:55 |
|                           | (b) (4)               |                      |

**US3802074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:55:48**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                                       | Time (GMT)           |
|----------------------------|--|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                           | 30 Apr 2021 09:45:22 |
| DataPoint Verified.        |  | 19 Apr 2021 20:25:30 |
| User signature succeeded.  | Judith Martin (b) (4)                      | 28 Jan 2021 18:19:31 |
| User entered '29 Sep 2020' | (b) (4)<br>Emily Carney (b) (4)<br>(b) (4) | 18 Nov 2020 18:08:55 |



**US3802074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:55:48**

[Start date completely unknown](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 30 Apr 2021 09:45:22 |
| DataPoint Verified.       |                       | 19 Apr 2021 20:25:30 |
| User signature succeeded. | Judith Martin (b) (4) | 28 Jan 2021 18:19:31 |
| User entered '0'          | (b) (4)               |                      |
|                           | Emily Carney (b) (4)  | 18 Nov 2020 18:08:55 |
|                           | (b) (4)               |                      |

**US3802074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:55:48**

[Ongoing?](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 30 Apr 2021 09:45:22 |
| DataPoint Verified.       |                       | 19 Apr 2021 20:25:30 |
| User signature succeeded. | Judith Martin (b) (4) | 28 Jan 2021 18:19:31 |
| User entered 'No (N)'     | (b) (4)               |                      |
|                           | Emily Carney (b) (4)  | 18 Nov 2020 18:08:55 |
|                           | (b) (4)               |                      |

**US3802074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:55:48**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 30 Apr 2021 09:45:22 |
| DataPoint Verified.       |  | 19 Apr 2021 20:25:30 |
| User signature succeeded. | Judith Martin (b) (4)                      | 28 Jan 2021 18:19:31 |
| User entered '1 Oct 2020' | (b) (4)<br>Emily Carney (b) (4)<br>(b) (4) | 18 Nov 2020 18:08:55 |

US3802074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:55:48

[Was this medication taken for solicited event?](#)

| Audit   | User                             | Time (GMT)           |
|---|----------------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)                 | 30 Apr 2021 09:45:22 |
| DataPoint Verified.   |                                  | 19 Apr 2021 20:25:30 |
| Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the HEADACHE AND PAIN AT INJECTION SITE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE AND PAIN AT INJECTION SITE did not meet the AE reporting criteria.<br>' canceled (Site from DM).    |                                  | 10 Mar 2021 09:07:11 |
| User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the HEADACHE AND PAIN AT INJECTION SITE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE AND PAIN AT INJECTION SITE did not meet the AE reporting criteria.<br>' (Site from DM). | (b) (4), (b) (6)                 | 10 Mar 2021 08:54:31 |
| User signature succeeded.   | Judith Martin (b) (4)<br>(b) (4) | 28 Jan 2021 18:19:31 |
| User entered 'Yes (Y)'  | Emily Carney (b) (4)<br>(b) (4)  | 18 Nov 2020 18:08:55 |

**US3802074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:55:48**

[Separate Dosage Number \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 30 Apr 2021 09:45:22 |
| User entered empty. | System           | 18 Nov 2020 18:08:55 |

**US3802074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:55:48**

[Interval Dosage Unit Number \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 30 Apr 2021 09:45:22 |
| User entered empty. | System           | 18 Nov 2020 18:08:55 |

US3802074

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:55:48**

[Interval Dosage Definition \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 30 Apr 2021 09:45:22 |
| User entered empty. | System           | 18 Nov 2020 18:08:55 |

US3802074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:55:48

Name of Medication

| Audit  | User                     | Time (GMT)           |
|--|--------------------------|----------------------|
| DataPoint Verified.  | (b) (4), (b) (6)         | 19 Apr 2021 20:25:30 |
| User closed query 'Per DM CLR: Was this medication added because the patient experienced a worsening or exacerbation of the medical history condition being treated? If yes, please add the worsening AE and applicable data to the AE eCRF or provide explanation for addition of new medication.' (Site from DM).                                  |                          | 16 Apr 2021 18:10:04 |
| Query 'Per DM CLR: Was this medication added because the patient experienced a worsening or exacerbation of the medical history condition being treated? If yes, please add the worsening AE and applicable data to the AE eCRF or provide explanation for addition of new medication.' answered with 'added' (Site from DM).                        | Melissa Andrasko (b) (4) | 07 Apr 2021 14:20:16 |
| User opened query 'Per DM CLR: Was this medication added because the patient experienced a worsening or exacerbation of the medical history condition being treated? If yes, please add the worsening AE and applicable data to the AE eCRF or provide explanation for addition of new medication.' (Site from DM).                                  | (b) (4), (b) (6)         | 07 Apr 2021 11:58:06 |
| User signature succeeded.  | Judith Martin (b) (4)    | 25 Mar 2021 17:58:59 |
| User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), COMBINATIONS, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS) AND DIURETICS, PRODUCT: HYDROCHLOROTHIAZIDE;LOSARTAN POTASSIUM, PRODUCTSYNONYM: LOSARTAN HCTZ - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)     | 25 Mar 2021 13:51:26 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.  | Coder Import (b) (4)     | 25 Mar 2021 13:51:26 |
| Data point term sent to Coder  | System                   | 25 Mar 2021 13:50:43 |
| User entered 'Losartan HCTZ'   | Lisa Vavro (b) (4)       | 25 Mar 2021 13:50:05 |

PRODUCTION RELEASE (v12.003  
EAB) (1725)

1815 of 1961



**US3802074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:55:48**

[Prophylaxis](#)

| Audit                     | User                                     | Time (GMT)           |
|---------------------------|--|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)                         | 19 Apr 2021 20:25:30 |
| User signature succeeded. | Judith Martin (b) (4)                    | 25 Mar 2021 17:58:59 |
| User entered 'No (N)'     | (b) (4)<br>Lisa Vavro (b) (4)<br>(b) (4) | 25 Mar 2021 13:50:05 |

**US3802074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:55:48**

[Indication](#)

| Audit                       | User                                     | Time (GMT)           |
|-----------------------------|--|----------------------|
| DataPoint Verified.         | (b) (4), (b) (6)                         | 19 Apr 2021 20:25:30 |
| User signature succeeded.   | Judith Martin (b) (4)                    | 25 Mar 2021 17:58:59 |
| User entered 'Hypertension' | (b) (4)<br>Lisa Vavro (b) (4)<br>(b) (4) | 25 Mar 2021 13:50:05 |

**US3802074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:55:48**

[Dose per administration](#)

| Audit                     | User                          | Time (GMT)           |
|---------------------------|-------------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)              | 19 Apr 2021 20:25:30 |
| User signature succeeded. | Judith Martin (b) (4)         | 25 Mar 2021 17:58:59 |
| User entered '50-12.5'    | (b) (4)<br>Lisa Vavro (b) (4) | 25 Mar 2021 13:50:05 |

**US3802074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:55:48**

[Dose unit](#)

| Audit                     | User                                     | Time (GMT)           |
|---------------------------|--|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)                         | 19 Apr 2021 20:25:30 |
| User signature succeeded. | Judith Martin (b) (4)                    | 25 Mar 2021 17:58:59 |
| User entered 'mg (mg)'    | (b) (4)<br>Lisa Vavro (b) (4)<br>(b) (4) | 25 Mar 2021 13:50:05 |

US3802074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:55:48

If dose unit is Other, specify

| Audit                     | User                                     | Time (GMT)           |
|---------------------------|--|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)                         | 19 Apr 2021 20:25:30 |
| User signature succeeded. | Judith Martin (b) (4)                    | 25 Mar 2021 17:58:59 |
| User entered empty.       | (b) (4)<br>Lisa Vavro (b) (4)<br>(b) (4) | 25 Mar 2021 13:50:05 |

**US3802074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:55:48**

[Frequency](#)

| Audit                          | User                          | Time (GMT)           |
|--------------------------------|-------------------------------|----------------------|
| DataPoint Verified.            | (b) (4), (b) (6)              | 19 Apr 2021 20:25:30 |
| User signature succeeded.      | Judith Martin (b) (4)         | 25 Mar 2021 17:58:59 |
| User entered 'once daily (QD)' | (b) (4)<br>Lisa Vavro (b) (4) | 25 Mar 2021 13:50:05 |
|                                | (b) (4)                       |                      |

**US3802074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:55:48**

[If frequency is Other, specify](#)

| Audit                     | User                                     | Time (GMT)           |
|---------------------------|--|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)                         | 19 Apr 2021 20:25:30 |
| User signature succeeded. | Judith Martin (b) (4)                    | 25 Mar 2021 17:58:59 |
| User entered empty.       | (b) (4)<br>Lisa Vavro (b) (4)<br>(b) (4) | 25 Mar 2021 13:50:05 |

**US3802074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:55:48**

[Route of administration](#)

| Audit                      | User                                     | Time (GMT)           |
|----------------------------|--|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                         | 19 Apr 2021 20:25:30 |
| User signature succeeded.  | Judith Martin (b) (4)                    | 25 Mar 2021 17:58:59 |
| User entered 'Oral (ORAL)' | (b) (4)<br>Lisa Vavro (b) (4)<br>(b) (4) | 25 Mar 2021 13:50:05 |



US3802074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:55:48

If route of administration is Other, specify

| Audit                     | User                                     | Time (GMT)           |
|---------------------------|--|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)                         | 19 Apr 2021 20:25:30 |
| User signature succeeded. | Judith Martin (b) (4)                    | 25 Mar 2021 17:58:59 |
| User entered empty.       | (b) (4)<br>Lisa Vavro (b) (4)<br>(b) (4) | 25 Mar 2021 13:50:05 |

**US3802074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:55:48**

[Start date \(dd MMM yyyy\)](#)

| Audit                     | User                          | Time (GMT)           |
|---------------------------|-------------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)              | 19 Apr 2021 20:25:30 |
| User signature succeeded. | Judith Martin (b) (4)         | 25 Mar 2021 17:58:59 |
| User entered '1 Mar 2021' | (b) (4)<br>Lisa Vavro (b) (4) | 25 Mar 2021 13:50:05 |
|                           | (b) (4)                       |                      |

**US3802074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:55:48**

[Start date completely unknown](#)

| Audit                     | User                                     | Time (GMT)           |
|---------------------------|--|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)                         | 19 Apr 2021 20:25:30 |
| User signature succeeded. | Judith Martin (b) (4)                    | 25 Mar 2021 17:58:59 |
| User entered '0'          | (b) (4)<br>Lisa Vavro (b) (4)<br>(b) (4) | 25 Mar 2021 13:50:05 |

**US3802074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:55:48**

[Ongoing?](#)

| Audit                     | User                                     | Time (GMT)           |
|---------------------------|--|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)                         | 19 Apr 2021 20:25:30 |
| User signature succeeded. | Judith Martin (b) (4)                    | 25 Mar 2021 17:58:59 |
| User entered 'Yes (Y)'    | (b) (4)<br>Lisa Vavro (b) (4)<br>(b) (4) | 25 Mar 2021 13:50:05 |

**US3802074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:55:48**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit                     | User                                     | Time (GMT)           |
|---------------------------|--|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)                         | 19 Apr 2021 20:25:30 |
| User signature succeeded. | Judith Martin (b) (4)                    | 25 Mar 2021 17:58:59 |
| User entered empty.       | (b) (4)<br>Lisa Vavro (b) (4)<br>(b) (4) | 25 Mar 2021 13:50:05 |

**US3802074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:55:48**

[Was this medication taken for solicited event?](#)

| Audit                     | User                                     | Time (GMT)           |
|---------------------------|--|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)                         | 19 Apr 2021 20:25:30 |
| User signature succeeded. | Judith Martin (b) (4)                    | 25 Mar 2021 17:58:59 |
| User entered 'No (N)'     | (b) (4)<br>Lisa Vavro (b) (4)<br>(b) (4) | 25 Mar 2021 13:50:05 |

**US3802074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:55:48**

[Separate Dosage Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 25 Mar 2021 13:50:05 |

**US3802074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:55:48**

[Interval Dosage Unit Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 25 Mar 2021 13:50:05 |



**US3802074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:55:48**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User   | Time (GMT)           |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 25 Mar 2021 13:50:05 |

US3802074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:55:48

[Name of Medication](#)

| Audit  | User                             | Time (GMT)           |
|--|----------------------------------|----------------------|
| DataPoint Verified.  | (b) (4), (b) (6)                 | 19 Apr 2021 20:25:30 |
| User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: QUINOLONE ANTIBACTERIALS, ATC: FLUOROQUINOLONES, PRODUCT: CIPROFLOXACIN - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4)  | 01 Apr 2021 13:32:04 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.   | Coder Import (b) (4)<br>(b) (4)  | 01 Apr 2021 13:32:04 |
| User signature succeeded.  | Judith Martin (b) (4)<br>(b) (4) | 31 Mar 2021 19:46:35 |
| Data point term sent to Coder  | System                           | 31 Mar 2021 15:27:56 |
| User entered 'Ciprofloxacin'   | Lisa Vavro (b) (4)<br>(b) (4)    | 31 Mar 2021 15:27:30 |

**US3802074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:55:48**

[Prophylaxis](#)

| Audit                     | User                                     | Time (GMT)           |
|---------------------------|--|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)                         | 19 Apr 2021 20:25:30 |
| User signature succeeded. | Judith Martin (b) (4)                    | 31 Mar 2021 19:46:35 |
| User entered 'No (N)'     | (b) (4)<br>Lisa Vavro (b) (4)<br>(b) (4) | 31 Mar 2021 15:27:30 |

**US3802074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:55:48**

[Indication](#)

| Audit   | User                          | Time (GMT)           |
|---|-------------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)              | 19 Apr 2021 20:25:30 |
| User signature succeeded.   | Judith Martin (b) (4)         | 31 Mar 2021 19:46:35 |
| User entered 'Prescribed for participant upon discharge from hospital after cholecystectomy surgery.' | (b) (4)<br>Lisa Vavro (b) (4) | 31 Mar 2021 15:27:30 |

**US3802074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:55:48**

[Dose per administration](#)

| Audit                     | User                                     | Time (GMT)           |
|---------------------------|--|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)                         | 19 Apr 2021 20:25:30 |
| User signature succeeded. | Judith Martin (b) (4)                    | 31 Mar 2021 19:46:35 |
| User entered '500'        | (b) (4)<br>Lisa Vavro (b) (4)<br>(b) (4) | 31 Mar 2021 15:27:30 |

**US3802074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:55:48**

[Dose unit](#)

| Audit                     | User                                     | Time (GMT)           |
|---------------------------|--|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)                         | 19 Apr 2021 20:25:30 |
| User signature succeeded. | Judith Martin (b) (4)                    | 31 Mar 2021 19:46:35 |
| User entered 'mg (mg)'    | (b) (4)<br>Lisa Vavro (b) (4)<br>(b) (4) | 31 Mar 2021 15:27:30 |

US3802074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:55:48

If dose unit is Other, specify

| Audit                     | User                                     | Time (GMT)           |
|---------------------------|--|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)                         | 19 Apr 2021 20:25:30 |
| User signature succeeded. | Judith Martin (b) (4)                    | 31 Mar 2021 19:46:35 |
| User entered empty.       | (b) (4)<br>Lisa Vavro (b) (4)<br>(b) (4) | 31 Mar 2021 15:27:30 |

**US3802074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:55:48**

[Frequency](#)

| Audit                            | User                                     | Time (GMT)           |
|----------------------------------|--|----------------------|
| DataPoint Verified.              | (b) (4), (b) (6)                         | 19 Apr 2021 20:25:30 |
| User signature succeeded.        | Judith Martin (b) (4)                    | 31 Mar 2021 19:46:35 |
| User entered 'twice daily (BID)' | (b) (4)<br>Lisa Vavro (b) (4)<br>(b) (4) | 31 Mar 2021 15:27:30 |



US3802074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:55:48

[If frequency is Other, specify](#)

| Audit                     | User                                     | Time (GMT)           |
|---------------------------|--|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)                         | 19 Apr 2021 20:25:30 |
| User signature succeeded. | Judith Martin (b) (4)                    | 31 Mar 2021 19:46:35 |
| User entered empty.       | (b) (4)<br>Lisa Vavro (b) (4)<br>(b) (4) | 31 Mar 2021 15:27:30 |

**US3802074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:55:48**

[Route of administration](#)

| Audit                      | User                                     | Time (GMT)           |
|----------------------------|--|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                         | 19 Apr 2021 20:25:30 |
| User signature succeeded.  | Judith Martin (b) (4)                    | 31 Mar 2021 19:46:35 |
| User entered 'Oral (ORAL)' | (b) (4)<br>Lisa Vavro (b) (4)<br>(b) (4) | 31 Mar 2021 15:27:30 |

US3802074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:55:48

If route of administration is Other, specify

| Audit                     | User                                     | Time (GMT)           |
|---------------------------|--|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)                         | 19 Apr 2021 20:25:30 |
| User signature succeeded. | Judith Martin (b) (4)                    | 31 Mar 2021 19:46:35 |
| User entered empty.       | (b) (4)<br>Lisa Vavro (b) (4)<br>(b) (4) | 31 Mar 2021 15:27:30 |

**US3802074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:55:48**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                                     | Time (GMT)           |
|----------------------------|--|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                         | 19 Apr 2021 20:25:30 |
| User signature succeeded.  | Judith Martin (b) (4)                    | 31 Mar 2021 19:46:35 |
| User entered '29 Mar 2021' | (b) (4)<br>Lisa Vavro (b) (4)<br>(b) (4) | 31 Mar 2021 15:27:30 |

**US3802074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:55:48**

[Start date completely unknown](#)

| Audit                     | User                                     | Time (GMT)           |
|---------------------------|--|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)                         | 19 Apr 2021 20:25:30 |
| User signature succeeded. | Judith Martin (b) (4)                    | 31 Mar 2021 19:46:35 |
| User entered '0'          | (b) (4)<br>Lisa Vavro (b) (4)<br>(b) (4) | 31 Mar 2021 15:27:30 |

US3802074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:55:48

[Ongoing?](#)

| Audit   | User                                | Time (GMT)           |
|---|-------------------------------------|----------------------|
| DataPoint Verified.                                       | (b) (4), (b) (6)                    | 19 Apr 2021 20:25:30 |
| User signature succeeded.                                 | Judith Martin (b) (4)               | 08 Apr 2021 18:35:41 |
| Signature has been broken.                                | (b) (4)<br>Melissa Andrasko (b) (4) | 07 Apr 2021 14:23:27 |
| User entered 'No (N)' reason for change: Data Entry Error | Melissa Andrasko (b) (4)            | 07 Apr 2021 14:23:27 |
| User signature succeeded.                                 | Judith Martin (b) (4)               | 31 Mar 2021 19:46:35 |
| User entered 'Yes (Y)'                                    | (b) (4)<br>Lisa Vavro (b) (4)       | 31 Mar 2021 15:27:30 |
|   | (b) (4)                             |                      |

US3802074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:55:48

If not Ongoing, End date (*dd MMM yyyy*)

| Audit  | User                     | Time (GMT)           |
|--|--------------------------|----------------------|
| DataPoint Verified.  | (b) (4), (b) (6)         | 19 Apr 2021 20:25:30 |
| User signature succeeded.                                      | Judith Martin (b) (4)    | 08 Apr 2021 18:35:41 |
| Signature has been broken.                                     | (b) (4)                  |                      |
|  | Melissa Andrasko (b) (4) | 07 Apr 2021 14:23:27 |
|  |                          |                      |
| User entered '05 Apr 2021' reason for change: Data Entry Error | Melissa Andrasko (b) (4) | 07 Apr 2021 14:23:27 |
|  |                          |                      |
| User signature succeeded.                                      | Judith Martin (b) (4)    | 31 Mar 2021 19:46:35 |
|  | (b) (4)                  |                      |
| User entered empty.  | Lisa Vavro (b) (4)       | 31 Mar 2021 15:27:30 |
|  | (b) (4)                  |                      |

US3802074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:55:48

[Was this medication taken for solicited event?](#)

| Audit                     | User                                     | Time (GMT)           |
|---------------------------|--|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)                         | 19 Apr 2021 20:25:30 |
| User signature succeeded. | Judith Martin (b) (4)                    | 31 Mar 2021 19:46:35 |
| User entered 'No (N)'     | (b) (4)<br>Lisa Vavro (b) (4)<br>(b) (4) | 31 Mar 2021 15:27:30 |



**US3802074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:55:48**

[Separate Dosage Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '2' | System | 31 Mar 2021 15:27:30 |

**US3802074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:55:48**

[Interval Dosage Unit Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 31 Mar 2021 15:27:30 |

**US3802074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:55:48**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User   | Time (GMT)           |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 31 Mar 2021 15:27:30 |

US3802074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:55:48

[Name of Medication](#)

| Audit  | User                                       | Time (GMT)           |
|--|--|----------------------|
| DataPoint Verified.  | (b) (4), (b) (6)                           | 19 Apr 2021 20:25:30 |
| User signature succeeded.  | Judith Martin (b) (4)                      | 31 Mar 2021 19:46:35 |
| User coded data point as ATC: NERVOUS<br>SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS,<br>ATC: NATURAL OPIUM ALKALOIDS,<br>PRODUCT: OXYCODONE - version<br>WHODrug-Global-B3\\202003. | (b) (4)<br>Coder Import (b) (4)<br>(b) (4) | 31 Mar 2021 15:30:10 |
| 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)            | 31 Mar 2021 15:30:10 |
| Data point term sent to Coder  | System                                     | 31 Mar 2021 15:28:57 |
| User entered 'oxycodone'   | Lisa Vavro (b) (4)<br>(b) (4)              | 31 Mar 2021 15:28:54 |

**US3802074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:55:48**

[Prophylaxis](#)

| Audit                     | User                                     | Time (GMT)           |
|---------------------------|--|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)                         | 19 Apr 2021 20:25:30 |
| User signature succeeded. | Judith Martin (b) (4)                    | 31 Mar 2021 19:46:35 |
| User entered 'No (N)'     | (b) (4)<br>Lisa Vavro (b) (4)<br>(b) (4) | 31 Mar 2021 15:28:54 |

**US3802074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:55:48**

[Indication](#)

| Audit                              | User                                     | Time (GMT)           |
|------------------------------------|--|----------------------|
| DataPoint Verified.                | (b) (4), (b) (6)                         | 19 Apr 2021 20:25:30 |
| User signature succeeded.          | Judith Martin (b) (4)                    | 31 Mar 2021 19:46:35 |
| User entered 'Post operative pain' | (b) (4)<br>Lisa Vavro (b) (4)<br>(b) (4) | 31 Mar 2021 15:28:54 |

**US3802074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:55:48**

[Dose per administration](#)

| Audit                     | User                                     | Time (GMT)           |
|---------------------------|--|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)                         | 19 Apr 2021 20:25:30 |
| User signature succeeded. | Judith Martin (b) (4)                    | 31 Mar 2021 19:46:35 |
| User entered '5'          | (b) (4)<br>Lisa Vavro (b) (4)<br>(b) (4) | 31 Mar 2021 15:28:54 |

**US3802074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:55:48**

[Dose unit](#)

| Audit                     | User                                     | Time (GMT)           |
|---------------------------|--|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)                         | 19 Apr 2021 20:25:30 |
| User signature succeeded. | Judith Martin (b) (4)                    | 31 Mar 2021 19:46:35 |
| User entered 'mg (mg)'    | (b) (4)<br>Lisa Vavro (b) (4)<br>(b) (4) | 31 Mar 2021 15:28:54 |



US3802074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:55:48

If dose unit is Other, specify

| Audit                     | User                                     | Time (GMT)           |
|---------------------------|--|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)                         | 19 Apr 2021 20:25:30 |
| User signature succeeded. | Judith Martin (b) (4)                    | 31 Mar 2021 19:46:35 |
| User entered empty.       | (b) (4)<br>Lisa Vavro (b) (4)<br>(b) (4) | 31 Mar 2021 15:28:54 |

**US3802074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:55:48**

[Frequency](#)

| Audit                          | User                          | Time (GMT)           |
|--------------------------------|-------------------------------|----------------------|
| DataPoint Verified.            | (b) (4), (b) (6)              | 19 Apr 2021 20:25:30 |
| User signature succeeded.      | Judith Martin (b) (4)         | 31 Mar 2021 19:46:35 |
| User entered 'as needed (PRN)' | (b) (4)<br>Lisa Vavro (b) (4) | 31 Mar 2021 15:28:54 |

US3802074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:55:48

[If frequency is Other, specify](#)

| Audit                     | User                                     | Time (GMT)           |
|---------------------------|--|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)                         | 19 Apr 2021 20:25:30 |
| User signature succeeded. | Judith Martin (b) (4)                    | 31 Mar 2021 19:46:35 |
| User entered empty.       | (b) (4)<br>Lisa Vavro (b) (4)<br>(b) (4) | 31 Mar 2021 15:28:54 |

**US3802074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:55:48**

[Route of administration](#)

| Audit                      | User                                     | Time (GMT)           |
|----------------------------|--|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                         | 19 Apr 2021 20:25:30 |
| User signature succeeded.  | Judith Martin (b) (4)                    | 31 Mar 2021 19:46:35 |
| User entered 'Oral (ORAL)' | (b) (4)<br>Lisa Vavro (b) (4)<br>(b) (4) | 31 Mar 2021 15:28:54 |

US3802074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:55:48

If route of administration is Other, specify

| Audit                     | User                                     | Time (GMT)           |
|---------------------------|--|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)                         | 19 Apr 2021 20:25:30 |
| User signature succeeded. | Judith Martin (b) (4)                    | 31 Mar 2021 19:46:35 |
| User entered empty.       | (b) (4)<br>Lisa Vavro (b) (4)<br>(b) (4) | 31 Mar 2021 15:28:54 |

**US3802074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:55:48**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                                     | Time (GMT)           |
|----------------------------|--|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                         | 19 Apr 2021 20:25:30 |
| User signature succeeded.  | Judith Martin (b) (4)                    | 31 Mar 2021 19:46:35 |
| User entered '29 Mar 2021' | (b) (4)<br>Lisa Vavro (b) (4)<br>(b) (4) | 31 Mar 2021 15:28:54 |

**US3802074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:55:48**

[Start date completely unknown](#)

| Audit                     | User                                     | Time (GMT)           |
|---------------------------|--|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)                         | 19 Apr 2021 20:25:30 |
| User signature succeeded. | Judith Martin (b) (4)                    | 31 Mar 2021 19:46:35 |
| User entered '0'          | (b) (4)<br>Lisa Vavro (b) (4)<br>(b) (4) | 31 Mar 2021 15:28:54 |

US3802074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:55:48

[Ongoing?](#)

| Audit   | User                     | Time (GMT)           |
|---|--------------------------|----------------------|
| DataPoint Verified.                                       | (b) (4), (b) (6)         | 19 Apr 2021 20:25:30 |
| User signature succeeded.                                 | Judith Martin (b) (4)    | 08 Apr 2021 18:35:41 |
| Signature has been broken.                                | (b) (4)                  |                      |
|   | Melissa Andrasko (b) (4) | 07 Apr 2021 14:24:16 |
|   |                          |                      |
| User entered 'No (N)' reason for change: Data Entry Error | Melissa Andrasko (b) (4) | 07 Apr 2021 14:24:16 |
|   |                          |                      |
| User signature succeeded.                                 | Judith Martin (b) (4)    | 31 Mar 2021 19:46:35 |
|   | (b) (4)                  |                      |
| User entered 'Yes (Y)'                                    | Lisa Vavro (b) (4)       | 31 Mar 2021 15:28:54 |
|   | (b) (4)                  |                      |



US3802074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:55:48

If not Ongoing, End date (*dd MMM yyyy*)

| Audit  | User                     | Time (GMT)           |
|--|--------------------------|----------------------|
| DataPoint Verified.  | (b) (4), (b) (6)         | 19 Apr 2021 20:25:30 |
| User signature succeeded.                                      | Judith Martin (b) (4)    | 08 Apr 2021 18:35:41 |
| Signature has been broken.                                     | (b) (4)                  |                      |
|  | Melissa Andrasko (b) (4) | 07 Apr 2021 14:24:16 |
|  |                          |                      |
| User entered '01 Apr 2021' reason for change: Data Entry Error | Melissa Andrasko (b) (4) | 07 Apr 2021 14:24:16 |
|  |                          |                      |
| User signature succeeded.                                      | Judith Martin (b) (4)    | 31 Mar 2021 19:46:35 |
|  | (b) (4)                  |                      |
| User entered empty.  | Lisa Vavro (b) (4)       | 31 Mar 2021 15:28:54 |
|  | (b) (4)                  |                      |

US3802074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:55:48

[Was this medication taken for solicited event?](#)

| Audit                     | User                                     | Time (GMT)           |
|---------------------------|--|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)                         | 19 Apr 2021 20:25:30 |
| User signature succeeded. | Judith Martin (b) (4)                    | 31 Mar 2021 19:46:35 |
| User entered 'No (N)'     | (b) (4)<br>Lisa Vavro (b) (4)<br>(b) (4) | 31 Mar 2021 15:28:54 |

**US3802074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:55:48**

[Separate Dosage Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 31 Mar 2021 15:28:54 |

**US3802074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:55:48**

[Interval Dosage Unit Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 31 Mar 2021 15:28:54 |

**US3802074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:55:48**

[Interval Dosage Definition \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 31 Mar 2021 15:28:54 |

US3802074

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 09:55:48

[Were any concomitant procedures performed?](#)

| Audit  | User                  | Time (GMT)           |
|--|-----------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)      | 03 May 2021 05:57:44 |
| DataPoint Verified.  |                       | 19 Apr 2021 19:45:28 |
| User signature succeeded.                                  | Judith Martin (b) (4) | 31 Mar 2021 19:46:35 |
| Signature has been broken.                                 | (b) (4)               |                      |
|  | Lisa Vavro (b) (4)    | 31 Mar 2021 15:36:09 |
|  | (b) (4)               |                      |
| User entered 'Yes (Y)' reason for change: Data Entry Error | Lisa Vavro (b) (4)    | 31 Mar 2021 15:36:09 |
|  | (b) (4)               |                      |
| User signature succeeded.                                  | Judith Martin (b) (4) | 13 Feb 2021 12:27:55 |
|  | (b) (4)               |                      |
| User entered 'No (N)'                                      | Emily Carney (b) (4)  | 08 Feb 2021 13:36:27 |
|  | (b) (4)               |                      |

**US3802074**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (1)**

**Generated On: 10 Jun 2021 09:55:48**

**Procedure/Surgery date** (*dd MMM yyyy*)

| Audit                      | User                          | Time (GMT)           |
|----------------------------|-------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)              | 19 Apr 2021 20:09:05 |
| User signature succeeded.  | Judith Martin (b) (4)         | 31 Mar 2021 19:46:35 |
| User entered '28 Mar 2021' | (b) (4)<br>Lisa Vavro (b) (4) | 31 Mar 2021 15:37:01 |
|                            | (b) (4)                       |                      |

US3802074

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:55:48

[Procedure/Surgery](#)

| Audit                          | User                          | Time (GMT)           |
|--------------------------------|-------------------------------|----------------------|
| DataPoint Verified.            | (b) (4), (b) (6)              | 19 Apr 2021 20:09:05 |
| User signature succeeded.      | Judith Martin (b) (4)         | 31 Mar 2021 19:46:35 |
| User entered 'cholecystectomy' | (b) (4)<br>Lisa Vavro (b) (4) | 31 Mar 2021 15:37:01 |
|                                | (b) (4)                       |                      |



US3802074

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:55:48

[Indication](#)

| Audit   | User                          | Time (GMT)           |
|---|-------------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)              | 19 Apr 2021 20:09:05 |
| User signature succeeded.   | Judith Martin (b) (4)         | 31 Mar 2021 19:46:35 |
| User closed query 'Indication is not Other, however specify has been provided. Please correct.' (Site from System). | (b) (4)<br>System             | 31 Mar 2021 15:37:23 |
| User entered 'Other (OTHER)' reason for change: Data Entry Error  | Lisa Vavro (b) (4)<br>(b) (4) | 31 Mar 2021 15:37:23 |
| User opened query 'Indication is not Other, however specify has been provided. Please correct.' (Site from System). | System                        | 31 Mar 2021 15:37:01 |
| User entered 'Adverse Event (AE)'   | Lisa Vavro (b) (4)<br>(b) (4) | 31 Mar 2021 15:37:01 |

US3802074

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:55:48

If indication is Other, specify

| Audit                                   | User                          | Time (GMT)           |
|---|-------------------------------|----------------------|
| DataPoint Verified.                     | (b) (4), (b) (6)              | 19 Apr 2021 20:09:05 |
| User signature succeeded.               | Judith Martin (b) (4)         | 31 Mar 2021 19:46:35 |
| User entered 'Increased Abdominal Pain' | (b) (4)<br>Lisa Vavro (b) (4) | 31 Mar 2021 15:37:01 |

**US3802074**

**Folder: SAE USA-US098-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:55:48**

[SAEID](#)

| Audit   | User                        | Time (GMT)           |
|---|-----------------------------|----------------------|
| DataPoint Verified.                                   | (b) (4), (b) (6)            | 23 Apr 2021 14:01:02 |
| User signature succeeded.                             | Judith Martin (b) (4)       | 01 Apr 2021 19:12:08 |
| Reviewed for Safety.                                  | (b) (4)<br>(b) (4), (b) (6) | 01 Apr 2021 15:47:47 |
| User entered<br>'USA-US098-2021-MRNA-1273-P301000003' | System                      | 01 Apr 2021 15:47:22 |

**US3802074**

**Folder: SAE USA-US098-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:55:48**

**Serious**

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 23 Apr 2021 14:01:02 |
| User signature succeeded. | Judith Martin (b) (4)       | 01 Apr 2021 19:12:08 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 01 Apr 2021 15:47:47 |
| User entered 'Yes (Y)'    | System                      | 01 Apr 2021 15:47:22 |

**US3802074**

**Folder: SAE USA-US098-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:55:48**

[Death](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 23 Apr 2021 14:01:02 |
| User signature succeeded. | Judith Martin (b) (4)       | 01 Apr 2021 19:12:08 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 01 Apr 2021 15:47:47 |
| User entered 'No (N)'     | System                      | 01 Apr 2021 15:47:22 |

**US3802074**

**Folder: SAE USA-US098-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:55:48**

[Life threatening](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 23 Apr 2021 14:01:02 |
| User signature succeeded. | Judith Martin (b) (4)       | 01 Apr 2021 19:12:08 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 01 Apr 2021 15:47:47 |
| User entered 'No (N)'     | System                      | 01 Apr 2021 15:47:22 |

**US3802074**

**Folder: SAE USA-US098-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:55:48**

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 23 Apr 2021 14:01:02 |
| User signature succeeded. | Judith Martin (b) (4)       | 01 Apr 2021 19:12:08 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 01 Apr 2021 15:47:47 |
| User entered 'Yes (Y)'    | System                      | 01 Apr 2021 15:47:22 |

US3802074

Folder: SAE USA-US098-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:55:48

[Persistent or significant disability or incapacity](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 23 Apr 2021 14:01:02 |
| User signature succeeded. | Judith Martin (b) (4)       | 01 Apr 2021 19:12:08 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 01 Apr 2021 15:47:47 |
| User entered 'No (N)'     | System                      | 01 Apr 2021 15:47:22 |



**US3802074**

**Folder: SAE USA-US098-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:55:48**

[Congenital anomaly or birth defect](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 23 Apr 2021 14:01:02 |
| User signature succeeded. | Judith Martin (b) (4)       | 01 Apr 2021 19:12:08 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 01 Apr 2021 15:47:47 |
| User entered 'No (N)'     | System                      | 01 Apr 2021 15:47:22 |

**US3802074**

**Folder: SAE USA-US098-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:55:48**

[Other medically important event](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 23 Apr 2021 14:01:02 |
| User signature succeeded. | Judith Martin (b) (4)       | 01 Apr 2021 19:12:08 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 01 Apr 2021 15:47:47 |
| User entered 'No (N)'     | System                      | 01 Apr 2021 15:47:22 |

US3802074

Folder: SAE USA-US098-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:55:48

[Investigator's First Name](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 23 Apr 2021 14:01:02 |
| User signature succeeded. | Judith Martin (b) (4)       | 01 Apr 2021 19:12:08 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 01 Apr 2021 15:47:47 |
| User entered 'Judith'     | System                      | 01 Apr 2021 15:47:22 |

US3802074

Folder: SAE USA-US098-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:55:48

[Investigator's Last Name](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 23 Apr 2021 14:01:02 |
| User signature succeeded. | Judith Martin (b) (4)       | 01 Apr 2021 19:12:08 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 01 Apr 2021 15:47:47 |
| User entered 'Martin'     | System                      | 01 Apr 2021 15:47:22 |

**US3802074**

**Folder: SAE USA-US098-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:55:48**

[Site Address: Street](#)

| Audit                         | User                        | Time (GMT)           |
|-------------------------------|-----------------------------|----------------------|
| DataPoint Verified.           | (b) (4), (b) (6)            | 23 Apr 2021 14:01:02 |
| User signature succeeded.     | Judith Martin (b) (4)       | 01 Apr 2021 19:12:08 |
| Reviewed for Safety.          | (b) (4)<br>(b) (4), (b) (6) | 01 Apr 2021 15:47:47 |
| User entered '3420 Fifth Ave' | System                      | 01 Apr 2021 15:47:22 |

**US3802074**

**Folder: SAE USA-US098-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:55:48**

[Site Address: City](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 23 Apr 2021 14:01:02 |
| User signature succeeded. | Judith Martin (b) (4)       | 01 Apr 2021 19:12:08 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 01 Apr 2021 15:47:47 |
| User entered 'Pittsburgh' | System                      | 01 Apr 2021 15:47:22 |

**US3802074**

**Folder: SAE USA-US098-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:55:48**

[Site Address: State](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)      | 23 Apr 2021 14:01:02 |
| User signature succeeded. | Judith Martin (b) (4) | 01 Apr 2021 19:12:08 |
| Reviewed for Safety.      | (b) (4), (b) (6)      | 01 Apr 2021 15:47:47 |
| User entered 'PA'         | System                | 01 Apr 2021 15:47:22 |

**US3802074**

**Folder: SAE USA-US098-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:55:48**

[Site Address: Postal Code](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 23 Apr 2021 14:01:02 |
| User signature succeeded. | Judith Martin (b) (4)       | 01 Apr 2021 19:12:08 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 01 Apr 2021 15:47:47 |
| User entered '15213'      | System                      | 01 Apr 2021 15:47:22 |



**US3802074**

**Folder: SAE USA-US098-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:55:48**

[Investigator Country](#)

| Audit                     | User             | Time (GMT)           |
|---------------------------|------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6) | 23 Apr 2021 14:01:02 |
| Reviewed for Safety.      | (b) (4), (b) (6) | 06 Apr 2021 12:41:04 |
| User signature succeeded. | (b) (4), (b) (6) | 01 Apr 2021 19:12:08 |
| User entered 'US'         | System           | 01 Apr 2021 15:47:59 |

**US3802074**

**Folder: SAE USA-US098-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:55:48**

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '4' | System | 19 Apr 2021 21:16:47 |
| User entered '3' | System | 08 Apr 2021 13:18:42 |
| User entered '2' | System | 06 Apr 2021 12:41:24 |
| User entered '1' | System | 01 Apr 2021 15:47:59 |

**US3802074**

**Folder: SAE USA-US098-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:55:48**

[SAEID](#)

| Audit   | User                        | Time (GMT)           |
|---|-----------------------------|----------------------|
| DataPoint Verified.                                   | (b) (4), (b) (6)            | 23 Apr 2021 14:01:02 |
| User signature succeeded.                             | Judith Martin (b) (4)       | 01 Apr 2021 19:12:08 |
| Reviewed for Safety.                                  | (b) (4)<br>(b) (4), (b) (6) | 01 Apr 2021 15:47:47 |
| User entered<br>'USA-US098-2021-MRNA-1273-P301000003' | System                      | 01 Apr 2021 15:47:22 |

**US3802074**

**Folder: SAE USA-US098-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:55:48**

[Serious](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 23 Apr 2021 14:01:02 |
| User signature succeeded. | Judith Martin (b) (4)       | 01 Apr 2021 19:12:08 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 01 Apr 2021 15:47:47 |
| User entered 'Yes (Y)'    | System                      | 01 Apr 2021 15:47:22 |

**US3802074**

**Folder: SAE USA-US098-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:55:48**

[Death](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 23 Apr 2021 14:01:02 |
| User signature succeeded. | Judith Martin (b) (4)       | 01 Apr 2021 19:12:08 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 01 Apr 2021 15:47:47 |
| User entered 'No (N)'     | System                      | 01 Apr 2021 15:47:22 |

**US3802074**

**Folder: SAE USA-US098-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:55:48**

[Life threatening](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 23 Apr 2021 14:01:02 |
| User signature succeeded. | Judith Martin (b) (4)       | 01 Apr 2021 19:12:08 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 01 Apr 2021 15:47:47 |
| User entered 'No (N)'     | System                      | 01 Apr 2021 15:47:22 |

US3802074

Folder: SAE USA-US098-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:55:48

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 23 Apr 2021 14:01:02 |
| User signature succeeded. | Judith Martin (b) (4)       | 01 Apr 2021 19:12:08 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 01 Apr 2021 15:47:47 |
| User entered 'Yes (Y)'    | System                      | 01 Apr 2021 15:47:22 |

US3802074

Folder: SAE USA-US098-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:55:48

[Persistent or significant disability or incapacity](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 23 Apr 2021 14:01:02 |
| User signature succeeded. | Judith Martin (b) (4)       | 01 Apr 2021 19:12:08 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 01 Apr 2021 15:47:47 |
| User entered 'No (N)'     | System                      | 01 Apr 2021 15:47:22 |



**US3802074**

**Folder: SAE USA-US098-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:55:48**

[Congenital anomaly or birth defect](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 23 Apr 2021 14:01:02 |
| User signature succeeded. | Judith Martin (b) (4)       | 01 Apr 2021 19:12:08 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 01 Apr 2021 15:47:47 |
| User entered 'No (N)'     | System                      | 01 Apr 2021 15:47:22 |

**US3802074**

**Folder: SAE USA-US098-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:55:48**

[Other medically important event](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 23 Apr 2021 14:01:02 |
| User signature succeeded. | Judith Martin (b) (4)       | 01 Apr 2021 19:12:08 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 01 Apr 2021 15:47:47 |
| User entered 'No (N)'     | System                      | 01 Apr 2021 15:47:22 |

US3802074

Folder: SAE USA-US098-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:55:48

[Investigator's First Name](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 23 Apr 2021 14:01:02 |
| User signature succeeded. | Judith Martin (b) (4)       | 01 Apr 2021 19:12:08 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 01 Apr 2021 15:47:47 |
| User entered 'Judith'     | System                      | 01 Apr 2021 15:47:22 |

US3802074

Folder: SAE USA-US098-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:55:48

[Investigator's Last Name](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 23 Apr 2021 14:01:02 |
| User signature succeeded. | Judith Martin (b) (4)       | 01 Apr 2021 19:12:08 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 01 Apr 2021 15:47:47 |
| User entered 'Martin'     | System                      | 01 Apr 2021 15:47:22 |

**US3802074**

**Folder: SAE USA-US098-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:55:48**

[Site Address: Street](#)

| Audit                         | User                        | Time (GMT)           |
|-------------------------------|-----------------------------|----------------------|
| DataPoint Verified.           | (b) (4), (b) (6)            | 23 Apr 2021 14:01:02 |
| User signature succeeded.     | Judith Martin (b) (4)       | 01 Apr 2021 19:12:08 |
| Reviewed for Safety.          | (b) (4)<br>(b) (4), (b) (6) | 01 Apr 2021 15:47:47 |
| User entered '3420 Fifth Ave' | System                      | 01 Apr 2021 15:47:22 |

**US3802074**

**Folder: SAE USA-US098-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:55:48**

[Site Address: City](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 23 Apr 2021 14:01:02 |
| User signature succeeded. | Judith Martin (b) (4)       | 01 Apr 2021 19:12:08 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 01 Apr 2021 15:47:47 |
| User entered 'Pittsburgh' | System                      | 01 Apr 2021 15:47:22 |

**US3802074**

**Folder: SAE USA-US098-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:55:48**

[Site Address: State](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 23 Apr 2021 14:01:02 |
| User signature succeeded. | Judith Martin (b) (4)       | 01 Apr 2021 19:12:08 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 01 Apr 2021 15:47:47 |
| User entered 'PA'         | System                      | 01 Apr 2021 15:47:22 |

**US3802074**

**Folder: SAE USA-US098-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:55:48**

[Site Address: Postal Code](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 23 Apr 2021 14:01:02 |
| User signature succeeded. | Judith Martin (b) (4)       | 01 Apr 2021 19:12:08 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 01 Apr 2021 15:47:47 |
| User entered '15213'      | System                      | 01 Apr 2021 15:47:22 |



**US3802074**

**Folder: SAE USA-US098-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:55:48**

[Investigator Country](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)      | 23 Apr 2021 14:01:02 |
| Reviewed for Safety.      |                       | 06 Apr 2021 12:41:04 |
| User signature succeeded. | Judith Martin (b) (4) | 01 Apr 2021 19:12:08 |
| User entered 'US'         | (b) (4)<br>System     | 01 Apr 2021 15:47:59 |

**US3802074**

**Folder: SAE USA-US098-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:55:48**

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '4' | System | 19 Apr 2021 21:16:47 |
| User entered '3' | System | 08 Apr 2021 13:18:42 |
| User entered '2' | System | 06 Apr 2021 12:41:24 |
| User entered '1' | System | 01 Apr 2021 15:47:59 |

**US3802074**

**Folder: SAE USA-US098-2021-MRNA-1273-P301000003**

**Form: Safety Report Form (1)**

**Generated On: 10 Jun 2021 09:55:48**

[Date of submission \(Pre-filled from custom function\)](#)

| Audit                            | User                  | Time (GMT)           |
|----------------------------------|-----------------------|----------------------|
| DataPoint Verified.              | (b) (4), (b) (6)      | 23 Apr 2021 14:01:02 |
| User signature succeeded.        | Judith Martin (b) (4) | 01 Apr 2021 19:12:08 |
| User entered '01/Apr/2021 11:47' | (b) (4)<br>System     | 01 Apr 2021 15:47:59 |

US3802074

Folder: SAE USA-US098-2021-MRNA-1273-P301000003

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:55:48

**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)            | 23 Apr 2021 14:01:02 |
| Reviewed for Safety.      |                             | 06 Apr 2021 12:41:04 |
| User signature succeeded. | Judith Martin (b) (4)       | 01 Apr 2021 19:12:08 |
| User entered 'I'          | (b) (4)<br>(b) (4), (b) (6) | 01 Apr 2021 15:47:59 |

**US3802074**

**Folder: SAE USA-US098-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:55:48**

[SAEID](#)

| Audit   | User                        | Time (GMT)           |
|---|-----------------------------|----------------------|
| DataPoint Verified.                                   | (b) (4), (b) (6)            | 23 Apr 2021 14:01:02 |
| User signature succeeded.                             | Judith Martin (b) (4)       | 01 Apr 2021 19:12:08 |
| Reviewed for Safety.                                  | (b) (4)<br>(b) (4), (b) (6) | 01 Apr 2021 15:47:47 |
| User entered<br>'USA-US098-2021-MRNA-1273-P301000003' | System                      | 01 Apr 2021 15:47:22 |

**US3802074**

**Folder: SAE USA-US098-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:55:48**

**Serious**

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 23 Apr 2021 14:01:02 |
| User signature succeeded. | Judith Martin (b) (4)       | 01 Apr 2021 19:12:08 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 01 Apr 2021 15:47:47 |
| User entered 'Yes (Y)'    | System                      | 01 Apr 2021 15:47:22 |

**US3802074**

**Folder: SAE USA-US098-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:55:48**

[Death](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 23 Apr 2021 14:01:02 |
| User signature succeeded. | Judith Martin (b) (4)       | 01 Apr 2021 19:12:08 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 01 Apr 2021 15:47:47 |
| User entered 'No (N)'     | System                      | 01 Apr 2021 15:47:22 |

**US3802074**

**Folder: SAE USA-US098-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:55:48**

[Life threatening](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 23 Apr 2021 14:01:02 |
| User signature succeeded. | Judith Martin (b) (4)       | 01 Apr 2021 19:12:08 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 01 Apr 2021 15:47:47 |
| User entered 'No (N)'     | System                      | 01 Apr 2021 15:47:22 |



US3802074

Folder: SAE USA-US098-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:55:48

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 23 Apr 2021 14:01:02 |
| User signature succeeded. | Judith Martin (b) (4)       | 01 Apr 2021 19:12:08 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 01 Apr 2021 15:47:47 |
| User entered 'Yes (Y)'    | System                      | 01 Apr 2021 15:47:22 |

US3802074

Folder: SAE USA-US098-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:55:48

[Persistent or significant disability or incapacity](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 23 Apr 2021 14:01:02 |
| User signature succeeded. | Judith Martin (b) (4)       | 01 Apr 2021 19:12:08 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 01 Apr 2021 15:47:47 |
| User entered 'No (N)'     | System                      | 01 Apr 2021 15:47:22 |

**US3802074**

**Folder: SAE USA-US098-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:55:48**

[Congenital anomaly or birth defect](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 23 Apr 2021 14:01:02 |
| User signature succeeded. | Judith Martin (b) (4)       | 01 Apr 2021 19:12:08 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 01 Apr 2021 15:47:47 |
| User entered 'No (N)'     | System                      | 01 Apr 2021 15:47:22 |

US3802074

Folder: SAE USA-US098-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:55:48

[Other medically important event](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 23 Apr 2021 14:01:02 |
| User signature succeeded. | Judith Martin (b) (4)       | 01 Apr 2021 19:12:08 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 01 Apr 2021 15:47:47 |
| User entered 'No (N)'     | System                      | 01 Apr 2021 15:47:22 |

US3802074

Folder: SAE USA-US098-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:55:48

[Investigator's First Name](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 23 Apr 2021 14:01:02 |
| User signature succeeded. | Judith Martin (b) (4)       | 01 Apr 2021 19:12:08 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 01 Apr 2021 15:47:47 |
| User entered 'Judith'     | System                      | 01 Apr 2021 15:47:22 |

US3802074

Folder: SAE USA-US098-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:55:48

[Investigator's Last Name](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 23 Apr 2021 14:01:02 |
| User signature succeeded. | Judith Martin (b) (4)       | 01 Apr 2021 19:12:08 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 01 Apr 2021 15:47:47 |
| User entered 'Martin'     | System                      | 01 Apr 2021 15:47:22 |

**US3802074**

**Folder: SAE USA-US098-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:55:48**

[Site Address: Street](#)

| Audit                         | User                        | Time (GMT)           |
|-------------------------------|-----------------------------|----------------------|
| DataPoint Verified.           | (b) (4), (b) (6)            | 23 Apr 2021 14:01:02 |
| User signature succeeded.     | Judith Martin (b) (4)       | 01 Apr 2021 19:12:08 |
| Reviewed for Safety.          | (b) (4)<br>(b) (4), (b) (6) | 01 Apr 2021 15:47:47 |
| User entered '3420 Fifth Ave' | System                      | 01 Apr 2021 15:47:22 |

**US3802074**

**Folder: SAE USA-US098-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:55:48**

[Site Address: City](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 23 Apr 2021 14:01:02 |
| User signature succeeded. | Judith Martin (b) (4)       | 01 Apr 2021 19:12:08 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 01 Apr 2021 15:47:47 |
| User entered 'Pittsburgh' | System                      | 01 Apr 2021 15:47:22 |



**US3802074**

**Folder: SAE USA-US098-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:55:48**

[Site Address: State](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 23 Apr 2021 14:01:02 |
| User signature succeeded. | Judith Martin (b) (4)       | 01 Apr 2021 19:12:08 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 01 Apr 2021 15:47:47 |
| User entered 'PA'         | System                      | 01 Apr 2021 15:47:22 |

**US3802074**

**Folder: SAE USA-US098-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:55:48**

[Site Address: Postal Code](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 23 Apr 2021 14:01:02 |
| User signature succeeded. | Judith Martin (b) (4)       | 01 Apr 2021 19:12:08 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 01 Apr 2021 15:47:47 |
| User entered '15213'      | System                      | 01 Apr 2021 15:47:22 |

**US3802074**

**Folder: SAE USA-US098-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:55:48**

[Investigator Country](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)      | 23 Apr 2021 14:01:02 |
| Reviewed for Safety.      |                       | 06 Apr 2021 12:41:04 |
| User signature succeeded. | Judith Martin (b) (4) | 01 Apr 2021 19:12:08 |
| User entered 'US'         | (b) (4)<br>System     | 01 Apr 2021 15:47:59 |

**US3802074**

**Folder: SAE USA-US098-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:55:48**

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '4' | System | 19 Apr 2021 21:16:47 |
| User entered '3' | System | 08 Apr 2021 13:18:42 |
| User entered '2' | System | 06 Apr 2021 12:41:24 |
| User entered '1' | System | 01 Apr 2021 15:47:59 |

**US3802074**

**Folder: SAE USA-US098-2021-MRNA-1273-P301000003**

**Form: Safety Report Form (2)**

**Generated On: 10 Jun 2021 09:55:48**

[Date of submission \(Pre-filled from custom function\)](#)

| Audit                            | User                  | Time (GMT)           |
|----------------------------------|-----------------------|----------------------|
| DataPoint Verified.              | (b) (4), (b) (6)      | 23 Apr 2021 14:01:02 |
| User signature succeeded.        | Judith Martin (b) (4) | 06 Apr 2021 15:48:46 |
| User entered '06/Apr/2021 07:41' | (b) (4)<br>System     | 06 Apr 2021 12:41:24 |

US3802074

Folder: SAE USA-US098-2021-MRNA-1273-P301000003

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:55:48

**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)      | 23 Apr 2021 14:01:02 |
|                           |                       |                      |
| User signature succeeded. | Judith Martin (b) (4) | 06 Apr 2021 15:48:46 |
|                           | (b) (4)               |                      |
| User entered 'I'          | (b) (4), (b) (6)      | 06 Apr 2021 12:41:24 |
|                           |                       |                      |

**US3802074**

**Folder: SAE USA-US098-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:55:48**

[SAEID](#)

| Audit   | User                        | Time (GMT)           |
|---|-----------------------------|----------------------|
| DataPoint Verified.                                   | (b) (4), (b) (6)            | 23 Apr 2021 14:01:02 |
| User signature succeeded.                             | Judith Martin (b) (4)       | 01 Apr 2021 19:12:08 |
| Reviewed for Safety.                                  | (b) (4)<br>(b) (4), (b) (6) | 01 Apr 2021 15:47:47 |
| User entered<br>'USA-US098-2021-MRNA-1273-P301000003' | System                      | 01 Apr 2021 15:47:22 |

**US3802074**

**Folder: SAE USA-US098-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:55:48**

[Serious](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 23 Apr 2021 14:01:02 |
| User signature succeeded. | Judith Martin (b) (4)       | 01 Apr 2021 19:12:08 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 01 Apr 2021 15:47:47 |
| User entered 'Yes (Y)'    | System                      | 01 Apr 2021 15:47:22 |



**US3802074**

**Folder: SAE USA-US098-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:55:48**

[Death](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 23 Apr 2021 14:01:02 |
| User signature succeeded. | Judith Martin (b) (4)       | 01 Apr 2021 19:12:08 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 01 Apr 2021 15:47:47 |
| User entered 'No (N)'     | System                      | 01 Apr 2021 15:47:22 |

**US3802074**

**Folder: SAE USA-US098-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:55:48**

[Life threatening](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 23 Apr 2021 14:01:02 |
| User signature succeeded. | Judith Martin (b) (4)       | 01 Apr 2021 19:12:08 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 01 Apr 2021 15:47:47 |
| User entered 'No (N)'     | System                      | 01 Apr 2021 15:47:22 |

**US3802074**

**Folder: SAE USA-US098-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:55:48**

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 23 Apr 2021 14:01:02 |
| User signature succeeded. | Judith Martin (b) (4)       | 01 Apr 2021 19:12:08 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 01 Apr 2021 15:47:47 |
| User entered 'Yes (Y)'    | System                      | 01 Apr 2021 15:47:22 |

US3802074

Folder: SAE USA-US098-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:55:48

[Persistent or significant disability or incapacity](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 23 Apr 2021 14:01:02 |
| User signature succeeded. | Judith Martin (b) (4)       | 01 Apr 2021 19:12:08 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 01 Apr 2021 15:47:47 |
| User entered 'No (N)'     | System                      | 01 Apr 2021 15:47:22 |

**US3802074**

**Folder: SAE USA-US098-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:55:48**

[Congenital anomaly or birth defect](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 23 Apr 2021 14:01:02 |
| User signature succeeded. | Judith Martin (b) (4)       | 01 Apr 2021 19:12:08 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 01 Apr 2021 15:47:47 |
| User entered 'No (N)'     | System                      | 01 Apr 2021 15:47:22 |

US3802074

Folder: SAE USA-US098-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:55:48

[Other medically important event](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 23 Apr 2021 14:01:02 |
| User signature succeeded. | Judith Martin (b) (4)       | 01 Apr 2021 19:12:08 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 01 Apr 2021 15:47:47 |
| User entered 'No (N)'     | System                      | 01 Apr 2021 15:47:22 |

US3802074

Folder: SAE USA-US098-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:55:48

[Investigator's First Name](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 23 Apr 2021 14:01:02 |
| User signature succeeded. | Judith Martin (b) (4)       | 01 Apr 2021 19:12:08 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 01 Apr 2021 15:47:47 |
| User entered 'Judith'     | System                      | 01 Apr 2021 15:47:22 |

US3802074

Folder: SAE USA-US098-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:55:48

[Investigator's Last Name](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 23 Apr 2021 14:01:02 |
| User signature succeeded. | Judith Martin (b) (4)       | 01 Apr 2021 19:12:08 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 01 Apr 2021 15:47:47 |
| User entered 'Martin'     | System                      | 01 Apr 2021 15:47:22 |



**US3802074**

**Folder: SAE USA-US098-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:55:48**

[Site Address: Street](#)

| Audit                         | User                        | Time (GMT)           |
|-------------------------------|-----------------------------|----------------------|
| DataPoint Verified.           | (b) (4), (b) (6)            | 23 Apr 2021 14:01:02 |
| User signature succeeded.     | Judith Martin (b) (4)       | 01 Apr 2021 19:12:08 |
| Reviewed for Safety.          | (b) (4)<br>(b) (4), (b) (6) | 01 Apr 2021 15:47:47 |
| User entered '3420 Fifth Ave' | System                      | 01 Apr 2021 15:47:22 |

**US3802074**

**Folder: SAE USA-US098-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:55:48**

[Site Address: City](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 23 Apr 2021 14:01:02 |
| User signature succeeded. | Judith Martin (b) (4)       | 01 Apr 2021 19:12:08 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 01 Apr 2021 15:47:47 |
| User entered 'Pittsburgh' | System                      | 01 Apr 2021 15:47:22 |

**US3802074**

**Folder: SAE USA-US098-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:55:48**

[Site Address: State](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 23 Apr 2021 14:01:02 |
| User signature succeeded. | Judith Martin (b) (4)       | 01 Apr 2021 19:12:08 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 01 Apr 2021 15:47:47 |
| User entered 'PA'         | System                      | 01 Apr 2021 15:47:22 |

**US3802074**

**Folder: SAE USA-US098-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:55:48**

[Site Address: Postal Code](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 23 Apr 2021 14:01:02 |
| User signature succeeded. | Judith Martin (b) (4)       | 01 Apr 2021 19:12:08 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 01 Apr 2021 15:47:47 |
| User entered '15213'      | System                      | 01 Apr 2021 15:47:22 |

**US3802074**

**Folder: SAE USA-US098-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:55:48**

[Investigator Country](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)      | 23 Apr 2021 14:01:02 |
| Reviewed for Safety.      |                       | 06 Apr 2021 12:41:04 |
| User signature succeeded. | Judith Martin (b) (4) | 01 Apr 2021 19:12:08 |
| User entered 'US'         | (b) (4)<br>System     | 01 Apr 2021 15:47:59 |

**US3802074**

**Folder: SAE USA-US098-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:55:48**

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '4' | System | 19 Apr 2021 21:16:47 |
| User entered '3' | System | 08 Apr 2021 13:18:42 |
| User entered '2' | System | 06 Apr 2021 12:41:24 |
| User entered '1' | System | 01 Apr 2021 15:47:59 |

**US3802074**

**Folder: SAE USA-US098-2021-MRNA-1273-P301000003**

**Form: Safety Report Form (3)**

**Generated On: 10 Jun 2021 09:55:48**

[Date of submission \(Pre-filled from custom function\)](#)

| Audit                            | User                  | Time (GMT)           |
|----------------------------------|-----------------------|----------------------|
| DataPoint Verified.              | (b) (4), (b) (6)      | 23 Apr 2021 14:01:02 |
| User signature succeeded.        | Judith Martin (b) (4) | 08 Apr 2021 18:35:41 |
| User entered '08/Apr/2021 06:18' | (b) (4)<br>System     | 08 Apr 2021 13:18:42 |

US3802074

Folder: SAE USA-US098-2021-MRNA-1273-P301000003

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 09:55:48

**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)            | 23 Apr 2021 14:01:02 |
| User signature succeeded. | Judith Martin (b) (4)       | 08 Apr 2021 18:35:41 |
| User entered 'I'          | (b) (4)<br>(b) (4), (b) (6) | 08 Apr 2021 13:18:42 |



**US3802074**

**Folder: SAE USA-US098-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:55:48**

[SAEID](#)

| Audit   | User                        | Time (GMT)           |
|---|-----------------------------|----------------------|
| DataPoint Verified.                                   | (b) (4), (b) (6)            | 23 Apr 2021 14:01:02 |
| User signature succeeded.                             | Judith Martin (b) (4)       | 01 Apr 2021 19:12:08 |
| Reviewed for Safety.                                  | (b) (4)<br>(b) (4), (b) (6) | 01 Apr 2021 15:47:47 |
| User entered<br>'USA-US098-2021-MRNA-1273-P301000003' | System                      | 01 Apr 2021 15:47:22 |

**US3802074**

**Folder: SAE USA-US098-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:55:48**

[Serious](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 23 Apr 2021 14:01:02 |
| User signature succeeded. | Judith Martin (b) (4)       | 01 Apr 2021 19:12:08 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 01 Apr 2021 15:47:47 |
| User entered 'Yes (Y)'    | System                      | 01 Apr 2021 15:47:22 |

**US3802074**

**Folder: SAE USA-US098-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:55:48**

[Death](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 23 Apr 2021 14:01:02 |
| User signature succeeded. | Judith Martin (b) (4)       | 01 Apr 2021 19:12:08 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 01 Apr 2021 15:47:47 |
| User entered 'No (N)'     | System                      | 01 Apr 2021 15:47:22 |

US3802074

Folder: SAE USA-US098-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:55:48

[Life threatening](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 23 Apr 2021 14:01:02 |
| User signature succeeded. | Judith Martin (b) (4)       | 01 Apr 2021 19:12:08 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 01 Apr 2021 15:47:47 |
| User entered 'No (N)'     | System                      | 01 Apr 2021 15:47:22 |

**US3802074**

**Folder: SAE USA-US098-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:55:48**

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 23 Apr 2021 14:01:02 |
| User signature succeeded. | Judith Martin (b) (4)       | 01 Apr 2021 19:12:08 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 01 Apr 2021 15:47:47 |
| User entered 'Yes (Y)'    | System                      | 01 Apr 2021 15:47:22 |

US3802074

Folder: SAE USA-US098-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:55:48

[Persistent or significant disability or incapacity](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 23 Apr 2021 14:01:02 |
| User signature succeeded. | Judith Martin (b) (4)       | 01 Apr 2021 19:12:08 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 01 Apr 2021 15:47:47 |
| User entered 'No (N)'     | System                      | 01 Apr 2021 15:47:22 |

**US3802074**

**Folder: SAE USA-US098-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:55:48**

[Congenital anomaly or birth defect](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 23 Apr 2021 14:01:02 |
| User signature succeeded. | Judith Martin (b) (4)       | 01 Apr 2021 19:12:08 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 01 Apr 2021 15:47:47 |
| User entered 'No (N)'     | System                      | 01 Apr 2021 15:47:22 |

**US3802074**

**Folder: SAE USA-US098-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:55:48**

[Other medically important event](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 23 Apr 2021 14:01:02 |
| User signature succeeded. | Judith Martin (b) (4)       | 01 Apr 2021 19:12:08 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 01 Apr 2021 15:47:47 |
| User entered 'No (N)'     | System                      | 01 Apr 2021 15:47:22 |



US3802074

Folder: SAE USA-US098-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:55:48

[Investigator's First Name](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 23 Apr 2021 14:01:02 |
| User signature succeeded. | Judith Martin (b) (4)       | 01 Apr 2021 19:12:08 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 01 Apr 2021 15:47:47 |
| User entered 'Judith'     | System                      | 01 Apr 2021 15:47:22 |

US3802074

Folder: SAE USA-US098-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:55:48

[Investigator's Last Name](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 23 Apr 2021 14:01:02 |
| User signature succeeded. | Judith Martin (b) (4)       | 01 Apr 2021 19:12:08 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 01 Apr 2021 15:47:47 |
| User entered 'Martin'     | System                      | 01 Apr 2021 15:47:22 |

**US3802074**

**Folder: SAE USA-US098-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:55:48**

[Site Address: Street](#)

| Audit                         | User                        | Time (GMT)           |
|-------------------------------|-----------------------------|----------------------|
| DataPoint Verified.           | (b) (4), (b) (6)            | 23 Apr 2021 14:01:02 |
| User signature succeeded.     | Judith Martin (b) (4)       | 01 Apr 2021 19:12:08 |
| Reviewed for Safety.          | (b) (4)<br>(b) (4), (b) (6) | 01 Apr 2021 15:47:47 |
| User entered '3420 Fifth Ave' | System                      | 01 Apr 2021 15:47:22 |

**US3802074**

**Folder: SAE USA-US098-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:55:48**

[Site Address: City](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 23 Apr 2021 14:01:02 |
| User signature succeeded. | Judith Martin (b) (4)       | 01 Apr 2021 19:12:08 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 01 Apr 2021 15:47:47 |
| User entered 'Pittsburgh' | System                      | 01 Apr 2021 15:47:22 |

**US3802074**

**Folder: SAE USA-US098-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:55:48**

[Site Address: State](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 23 Apr 2021 14:01:02 |
| User signature succeeded. | Judith Martin (b) (4)       | 01 Apr 2021 19:12:08 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 01 Apr 2021 15:47:47 |
| User entered 'PA'         | System                      | 01 Apr 2021 15:47:22 |

**US3802074**

**Folder: SAE USA-US098-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:55:48**

[Site Address: Postal Code](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 23 Apr 2021 14:01:02 |
| User signature succeeded. | Judith Martin (b) (4)       | 01 Apr 2021 19:12:08 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 01 Apr 2021 15:47:47 |
| User entered '15213'      | System                      | 01 Apr 2021 15:47:22 |

**US3802074**

**Folder: SAE USA-US098-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:55:48**

[Investigator Country](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)      | 23 Apr 2021 14:01:02 |
| Reviewed for Safety.      |                       | 06 Apr 2021 12:41:04 |
| User signature succeeded. | Judith Martin (b) (4) | 01 Apr 2021 19:12:08 |
| User entered 'US'         | (b) (4)<br>System     | 01 Apr 2021 15:47:59 |

**US3802074**

**Folder: SAE USA-US098-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:55:48**

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '4' | System | 19 Apr 2021 21:16:47 |
| User entered '3' | System | 08 Apr 2021 13:18:42 |
| User entered '2' | System | 06 Apr 2021 12:41:24 |
| User entered '1' | System | 01 Apr 2021 15:47:59 |



**US3802074**

**Folder: SAE USA-US098-2021-MRNA-1273-P301000003**

**Form: Safety Report Form (4)**

**Generated On: 10 Jun 2021 09:55:48**

[Date of submission \(Pre-filled from custom function\)](#)

| Audit                            | User                  | Time (GMT)           |
|----------------------------------|-----------------------|----------------------|
| DataPoint Verified.              | (b) (4), (b) (6)      | 23 Apr 2021 14:01:02 |
| User signature succeeded.        | Judith Martin (b) (4) | 20 Apr 2021 15:11:04 |
| User entered '19/Apr/2021 17:16' | (b) (4)<br>System     | 19 Apr 2021 21:16:47 |

US3802074

Folder: SAE USA-US098-2021-MRNA-1273-P301000003

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 09:55:48

**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)            | 23 Apr 2021 14:01:02 |
| User signature succeeded. | Judith Martin (b) (4)       | 20 Apr 2021 15:11:04 |
| User entered 'I'          | (b) (4)<br>(b) (4), (b) (6) | 19 Apr 2021 21:16:47 |