

US3902021 (Prod: Synexus - Optimal Research - Melbourne)

Generated By: KC Joubran

Generated On: 10 Jun 2021 10:17:24

All time stamps listed in this document are displayed in GMT

US3902021

Form: Participant Creation

Data signed: (b) (4) 30 Mar 2021 18:10:54

Generated On: 10 Jun 2021 10:17:24

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[Participant ID](#)

US3902021

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

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US3902021

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 30 Mar 2021 18:10:55

Generated On: 10 Jun 2021 10:17:24

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

|                          |             |
|--------------------------|-------------|
| Visit date (dd MMM yyyy) | 02 SEP 2020 |
|--------------------------|-------------|

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

|            |      |
|------------|------|
| Folder OID | SCRN |
|------------|------|

US3902021

Folder: Screening

Form: Demographics

Data signed: (b) (4) 30 Mar 2021 18:10:55

Generated On: 10 Jun 2021 10:17:24

|   |  |
|---|--|
| Date of Birth (MMM yyyy)                  | (b) (6) 1982   |
| Age                                       | 38   |
| Age Units                                 | YEARS  |
| Age (Derived)                             | 38   |
| Sex                                       | Female <input checked="" type="radio"/><br>Male <input type="radio"/>  |
| Ethnicity                                 | Hispanic or Latino <input checked="" type="radio"/><br>Not Hispanic or Latino <input 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  |

US3902021

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 30 Mar 2021 18:10:55

Generated On: 10 Jun 2021 10:17:24

Date of Informed Consent (*dd MMM yyyy*) 2 SEP 2020

Month and Year of Informed Consent (derived) SEP 2020

Year of Informed Consent (derived) 2020

Protocol Version

|             |                                  |
|-------------|----------------------------------|
| Amendment 1 | <input type="radio"/>            |
| Amendment 2 | <input type="radio"/>            |
| Amendment 3 | <input checked="" type="radio"/> |
| Amendment 4 | <input type="radio"/>            |
| Amendment 5 | <input type="radio"/>            |

Was participant enrolled in the study?

|     |                                  |
|-----|----------------------------------|
| Yes | <input checked="" type="radio"/> |
| No  | <input type="radio"/>            |

If No, indicate reason for screen fail

|                     |                       |
|---------------------|-----------------------|
| Withdrew Consent    | <input type="radio"/> |
| Inclusion/Exclusion | <input type="radio"/> |
| Cohort Full         | <input type="radio"/> |
| Other               | <input type="radio"/> |

If reason for screen fail is Other, specify \_\_\_\_\_

Was this participant screened previously?

|     |                                  |
|-----|----------------------------------|
| Yes | <input type="radio"/>            |
| No  | <input checked="" type="radio"/> |

If Yes, previous participant number \_\_\_\_\_

Enrollment Trigger 1

US3902021

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 30 Mar 2021 18:10:55

Generated On: 10 Jun 2021 10:17:24

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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US3902021

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 30 Mar 2021 18:10:55

Generated On: 10 Jun 2021 10:17:24

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Were any significant conditions reported?

Yes ☐

No ☒

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US3902021

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 30 Mar 2021 18:10:55

Generated On: 10 Jun 2021 10:17:24

|   |                                      |
|---|--------------------------------------|
| Were vital signs assessed?                | Yes <input checked="" type="radio"/> |
|   | No <input type="radio"/>             |
| Date of assessment ( <i>dd MMM yyyy</i> ) | 02 SEP 2020                          |
| Time of assessment ( <i>00:00-23:59</i> ) | 16:48 (24 HR)                        |
| Vital Signs Date and Time (derived)       | 02 SEP 2020 16:48                    |
| Height ( <i>xxx.x</i> )                   | 64 in                                |
| Weight ( <i>xxx.x</i> )                   | 134 lb                               |
| BMI ( <i>xxx.x</i> )                      | 23.04914 kg/m <sup>2</sup>           |
| BMI units                                 | KG/M2                                |
| Temperature ( <i>xxx.x</i> )              | ND - Not Done                        |
| Route of measurement                      | Oral <input type="radio"/>           |
|   | Axillary <input type="radio"/>       |
|   | Other <input type="radio"/>          |
| If Other, specify                         |                                      |
| Pulse ( <i>xxx</i> )                      | ND - Not Done                        |
| Pulse units                               | BPM                                  |
| Respiratory Rate ( <i>xxx</i> )           | ND - Not Done                        |
| Respiratory Rate units                    | BREATHS/MIN                          |
| Systolic Blood Pressure ( <i>xxx</i> )    | ND - Not Done                        |
| Systolic Blood Pressure units             | MMHG                                 |
| Diastolic Blood Pressure ( <i>xxx</i> )   | ND - Not Done                        |
| Diastolic Blood Pressure units            | MMHG                                 |
| Height (derived)                          |                                      |
| Weight (derived)                          |                                      |



US3902021

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 30 Mar 2021 18:10:55

Generated On: 10 Jun 2021 10:17:24

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

02 SEP 2020

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

US3902021

Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 30 Mar 2021 18:10:55

Generated On: 10 Jun 2021 10:17:24

Date of assessment (dd MMM yyyy) 02 SEP 2020

Is the participant of childbearing potential? Yes ☒  
No ☐

If No, what is the reason? Surgically sterile ☐  
Post-menopausal ☐  
Partner medically sterile ☐  
Not reached age of Menarche ☐  
Other ☐

If Partner medically sterile or Other, specify \_\_\_\_\_  
If Surgically sterile, date of surgery (dd MMM yyyy) \_\_\_\_\_  
Date of surgery unknown False  
If Post-menopausal, date of last menstruation (dd MMM yyyy) \_\_\_\_\_  
Date of last menstruation unknown False

US3902021

Folder: Screening

Form: Pregnancy Test

Data signed: (b) (4) 30 Mar 2021 18:10:55

Generated On: 10 Jun 2021 10:17:24

|                                     |   |
|-------------------------------------|---|
| Was the pregnancy test performed?   | Yes <input checked="" type="radio"/>      |
|                                     | No <input type="radio"/>                  |
| Date of test ( <i>dd MMM yyyy</i> ) | 02 SEP 2020                               |
| Test performed                      | Urine <input checked="" type="radio"/>    |
|                                     | Serum <input type="radio"/>               |
| Result                              | Positive <input type="radio"/>            |
|                                     | Negative <input checked="" type="radio"/> |
| Was FSH sample collected?           | Yes <input type="radio"/>                 |
|                                     | No <input checked="" type="radio"/>       |
| Collection date                     |   |
| Collection time                     |   |
| Collection date and time (derived)  |   |

US3902021

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 30 Mar 2021 18:10:55

Generated On: 10 Jun 2021 10:17:24

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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**

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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

US3902021

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 30 Mar 2021 18:10:55

Generated On: 10 Jun 2021 10:17:24

|  |                                      |
|--|--------------------------------------|
| <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)  | False                                |
| <b>Other</b>   | True                                 |
| <b>Specify</b>   | CONDOMINIUM WITH ONE<br>OTHER PERSON |

US3902021

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 30 Mar 2021 18:10:56

Generated On: 10 Jun 2021 10:17:24

|   |   |
|---|---|
| Was this visit performed?                                       | Yes <input checked="" type="radio"/>    |
|   | No <input type="radio"/>                |
| Visit date (dd MMM yyyy)  | 02 SEP 2020                             |
| Was visit performed at the participant's home or at the clinic? | Home <input type="radio"/>              |
|   | Clinic <input checked="" type="radio"/> |
| Folder OID  | VISIT1                                  |

US3902021

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 30 Mar 2021 18:10:56

Generated On: 10 Jun 2021 10:17:24

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

What was the participant's randomization number? 111222

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 ☒

US3902021

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 30 Mar 2021 18:10:56

Generated On: 10 Jun 2021 10:17:24

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



US3902021

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 30 Mar 2021 18:10:56

Generated On: 10 Jun 2021 10:17:24

|                                     |  |
|-------------------------------------|--|
| Height                              | ND - Not Done  |
| Weight                              | ND - Not Done  |
| Timepoint                           | Pre-Dose <input checked="" type="radio"/><br>Post-Dose <input type="radio"/>                           |
| Were vital signs assessed?          | Yes <input checked="" type="radio"/><br>No <input type="radio"/>                                       |
| Date of assessment (dd MMM yyyy)    | 02 SEP 2020  |
| Time of assessment (00:00-23:59)    | 16:48 (24 HR)  |
| Vital Signs Date and Time (derived) | 02 SEP 2020 16:48  |
| Temperature (xxx.x)                 | 97.3 F   |
| Route of measurement                | Oral <input checked="" type="radio"/><br>Axillary <input type="radio"/><br>Other <input type="radio"/> |
| If Other, specify                   |  |
| Pulse (xxx)                         | 67 beats/min   |
| Pulse units                         | BPM  |
| Respiratory Rate (xxx)              | 16 breaths/min   |
| Respiratory Rate units              | BREATHS/MIN  |
| Systolic Blood Pressure (xxx)       | 103 mmHg   |
| Systolic Blood Pressure units       | MMHG   |
| Diastolic Blood Pressure (xxx)      | 81 mmHg  |
| Diastolic Blood Pressure units      | MMHG   |

US3902021

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 30 Mar 2021 18:10:56

Generated On: 10 Jun 2021 10:17:24

|                                     |  |
|-------------------------------------|--|
| Height                              | ND - Not Done  |
| Weight                              | ND - Not Done  |
| Timepoint                           | Pre-Dose <input type="radio"/><br>Post-Dose <input checked="" type="radio"/>                           |
| Were vital signs assessed?          | Yes <input checked="" type="radio"/><br>No <input type="radio"/>                                       |
| Date of assessment (dd MMM yyyy)    | 02 SEP 2020  |
| Time of assessment (00:00-23:59)    | 19:15 (24 HR)  |
| Vital Signs Date and Time (derived) | 02 SEP 2020 19:15  |
| Temperature (xxx.x)                 | 97.3 F   |
| Route of measurement                | Oral <input checked="" type="radio"/><br>Axillary <input type="radio"/><br>Other <input type="radio"/> |
| If Other, specify                   |  |
| Pulse (xxx)                         | 68 beats/min   |
| Pulse units                         | BPM  |
| Respiratory Rate (xxx)              | 16 breaths/min   |
| Respiratory Rate units              | BREATHS/MIN  |
| Systolic Blood Pressure (xxx)       | 98 mmHg  |
| Systolic Blood Pressure units       | MMHG   |
| Diastolic Blood Pressure (xxx)      | 66 mmHg  |
| Diastolic Blood Pressure units      | MMHG   |

US3902021

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 30 Mar 2021 18:10:56

Generated On: 10 Jun 2021 10:17:24

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

02 SEP 2020

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

US3902021

Folder: Visit 1 Day 1

Form: Pregnancy Test

Data signed: (b) (4) 30 Mar 2021 18:10:56

Generated On: 10 Jun 2021 10:17:24

Was the pregnancy test performed? Yes ☐  
No ☒

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

Test performed Urine ☐  
Serum ☐

Result Positive ☐  
Negative ☐

Was FSH sample collected? Yes ☐  
No ☒

Collection date \_\_\_\_\_

Collection time \_\_\_\_\_

Collection date and time (derived) \_\_\_\_\_

US3902021

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 30 Mar 2021 18:10:56

Generated On: 10 Jun 2021 10:17:24

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) 02 SEP 2020

What was the treatment time? (00:00-23:59) 18:40 (24 HR)

Treatment Date and Time (derived) 02 SEP 2020 18:40

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

US3902021

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 30 Mar 2021 18:10:56

Generated On: 10 Jun 2021 10:17:24

|                                    |                                      |
|------------------------------------|--------------------------------------|
| Was the sample collected?          | Yes <input checked="" type="radio"/> |
|                                    | No <input type="radio"/>             |
| Collection date (dd MMM yyyy)      | 2 SEP 2020                           |
| Collection time (00:00-23:59)      | 18:03 (24 HR)                        |
| Collection date and time (derived) | 2 SEP 2020 18:03                     |

US3902021

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 30 Mar 2021 18:10:56

Generated On: 10 Jun 2021 10:17:24

|                               |                           |                                 |                                    |
|-------------------------------|---------------------------|---------------------------------|------------------------------------|
| Collection date (dd MMM yyyy) |                           |                                 | 02 SEP 2020                        |
| Lab Test                      | Was the sample collected? | Collection time (00:00 - 23:59) | Collection date and time (derived) |
| Nasopharyngeal Swab 1         | Yes                       | 18:04                           | 02 SEP 2020 18:04                  |
| Nasopharyngeal Swab 2         | No                        |                                 |                                    |

US3902021

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 30 Mar 2021 18:10:56

Generated On: 10 Jun 2021 10:17:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3902021

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 10:17:24

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒  
No ☐

Please record your **TEMPERATURE** in °F

97.3 °F

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

Yes ☐  
No ☒

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

PC Time Stamp 02 SEP 2020 19:12

PC Open Date & Time 02 SEP 2020 19:00

PC Close Date & Time 02 SEP 2020 21:30

US3902021

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 10:17:24

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.2 °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        | 03 SEP 2020 08:48 |
| PC Open Date & Time  | 02 SEP 2020 22:25 |
| PC Close Date & Time | 03 SEP 2020 11:59 |

US3902021

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 10:17:24

**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

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

04 SEP 2020 09:45

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3902021

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 10:17:24

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

05 SEP 2020 09:22

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3902021

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 10:17:24

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °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

06 SEP 2020 09:40

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3902021

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 10:17:24

**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

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3902021

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 10:17:24

**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

98.6 °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

07 SEP 2020 12:42

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3902021

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 10:17:24

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

09 SEP 2020 09:36

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59



US3902021

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 10:17:24

**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

02 SEP 2020 19:12

PC Open Date & Time

02 SEP 2020 19:00

PC Close Date & Time

02 SEP 2020 21:30

US3902021

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 10:17:24

**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

03 SEP 2020 08:37

PC Open Date & Time

02 SEP 2020 22:25

PC Close Date & Time

03 SEP 2020 11:59

US3902021

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 10:17:24

**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

04 SEP 2020 09:45

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3902021

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 10:17:24

**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

05 SEP 2020 09:22

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3902021

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 10:17:24

**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

06 SEP 2020 09:41

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3902021

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 10:17:24

**TIMEPOINT**

DAY 5

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3902021

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 10:17:24

**TIMEPOINT**

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

07 SEP 2020 12:41

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3902021

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 10:17:24

**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

09 SEP 2020 09:36

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59



US3902021

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 10:17:24

**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 ☐

US3902021

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 10:17:24

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

No ☒

Yes ☐

|                      |                   |
|----------------------|-------------------|
| PC Time stamp        | 02 SEP 2020 19:13 |
| PC Open Date & Time  | 02 SEP 2020 19:00 |
| PC Close Date & Time | 02 SEP 2020 21:30 |

US3902021

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 10:17:24

**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 ☐

US3902021

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 10:17:24

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

No ☒

Yes ☐

|               |                   |
|---------------|-------------------|
| PC Time stamp | 03 SEP 2020 08:38 |
|---------------|-------------------|

|                     |                   |
|---------------------|-------------------|
| PC Open Date & Time | 02 SEP 2020 22:25 |
|---------------------|-------------------|

|                      |                   |
|----------------------|-------------------|
| PC Close Date & Time | 03 SEP 2020 11:59 |
|----------------------|-------------------|

US3902021

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 10:17:24

**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 ☒

US3902021

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 10:17:24

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 04 SEP 2020 09:46 |
| PC Open Date & Time          | 03 SEP 2020 12:00 |
| PC Close Date & Time         | 04 SEP 2020 11:59 |

US3902021

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 10:17:24

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 ☒

PRODUCTION RELEASE (v12.003

46 of 1879

EAB) (1725)

US3902021

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 10:17:24

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 05 SEP 2020 09:23 |
| PC Open Date & Time          | 04 SEP 2020 12:00 |
| PC Close Date & Time         | 05 SEP 2020 11:59 |



US3902021

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 10:17:24

**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 ☒

US3902021

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 10:17:24

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 06 SEP 2020 09:42 |
| PC Open Date & Time          | 05 SEP 2020 12:00 |
| PC Close Date & Time         | 06 SEP 2020 11:59 |

US3902021

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 10:17:24

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 ☐

US3902021

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 10:17:24

Yes ☐

PC Time stamp

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3902021

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 10:17:24

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 ☒

PRODUCTION RELEASE (v12.003

52 of 1879

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US3902021

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 10:17:24

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

US3902021

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 10:17:24

**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 ☒

US3902021

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 10:17:24

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 09 SEP 2020 09:37 |
| PC Open Date & Time          | 08 SEP 2020 12:00 |
| PC Close Date & Time         | 09 SEP 2020 11:59 |



US3902021

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(8)

Generated On: 10 Jun 2021 10:17:24

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

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3902021

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(9)

Generated On: 10 Jun 2021 10:17:24

---

**TIMEPOINT**

DAY 9

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

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily  
activity ☐

---

PC Time stamp 11 SEP 2020 09:31

PC Open Date & Time 10 SEP 2020 12:00

---

PC Close Date & Time 11 SEP 2020 11:59

---

US3902021

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(10)

Generated On: 10 Jun 2021 10:17:24

TIMEPOINT

DAY 10

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

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

PC Time stamp

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3902021

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(11)

Generated On: 10 Jun 2021 10:17:24

---

**TIMEPOINT**

DAY 11

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

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

---

US3902021

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 10 Jun 2021 10:17:24

|   |                              |
|---|------------------------------|
| <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 type="checkbox"/>  |
|   | Yes <input type="checkbox"/> |
| PC Time stamp   |                              |
| PC Open Date & Time   | 09 SEP 2020 12:00            |
| PC Close Date & Time  | 10 SEP 2020 11:59            |

US3902021

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(9)

Generated On: 10 Jun 2021 10:17:24

|   |  |
|---|--|
| <b>TIMEPOINT</b>  | DAY 9  |
| Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms? | No <input checked="" type="radio"/><br>Yes <input type="radio"/> |
| PC Time stamp   | 11 SEP 2020 09:31  |
| PC Open Date & Time   | 10 SEP 2020 12:00  |
| PC Close Date & Time  | 11 SEP 2020 11:59  |

US3902021

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(10)

Generated On: 10 Jun 2021 10:17:24

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

US3902021

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(11)

Generated On: 10 Jun 2021 10:17:24

|   |                              |
|---|------------------------------|
| <b>TIMEPOINT</b>  | DAY 11                       |
| Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms? | No <input type="checkbox"/>  |
|   | Yes <input type="checkbox"/> |
| PC Time stamp   |                              |
| PC Open Date & Time   | 12 SEP 2020 12:00            |
| PC Close Date & Time  | 13 SEP 2020 11:59            |



US3902021

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 30 Mar 2021 18:10:55

Generated On: 10 Jun 2021 10:17:24

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 9 SEP 2020

Please select one status for the follow-up contact  
Contact Made ☒  
Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3902021

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 30 Mar 2021 18:10:55

Generated On: 10 Jun 2021 10:17:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3902021

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 30 Mar 2021 18:10:55

Generated On: 10 Jun 2021 10:17:24

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*

US3902021

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 30 Mar 2021 18:10:55

Generated On: 10 Jun 2021 10:17:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3902021

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 30 Mar 2021 18:10:55

Generated On: 10 Jun 2021 10:17:24

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3902021

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 30 Mar 2021 18:10:55

Generated On: 10 Jun 2021 10:17:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3902021

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 30 Mar 2021 18:11:35

Generated On: 10 Jun 2021 10:17:24

|   |   |
|---|---|
| Was this visit performed?                                       | Yes <input checked="" type="radio"/>    |
|   | No <input type="radio"/>                |
| Visit date (dd MMM yyyy)  | 29 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                                  |

US3902021

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 30 Mar 2021 18:11:35

Generated On: 10 Jun 2021 10:17:24

|                                     |   |
|-------------------------------------|---|
| 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)    | 29 SEP 2020                               |
| Time of assessment (00:00-23:59)    | 15:18 (24 HR)                             |
| Vital Signs Date and Time (derived) | 29 SEP 2020 15:18                         |
| Temperature (xxx.x)                 | 97.7 F                                    |
| Route of measurement                | Oral <input checked="" type="radio"/>     |
|                                     | Axillary <input type="radio"/>            |
|                                     | Other <input type="radio"/>               |
| If Other, specify                   |   |
| Pulse (xxx)                         | 71 beats/min                              |
| Pulse units                         | BPM                                       |
| Respiratory Rate (xxx)              | 16 breaths/min                            |
| Respiratory Rate units              | BREATHS/MIN                               |
| Systolic Blood Pressure (xxx)       | 108 mmHg                                  |
| Systolic Blood Pressure units       | MMHG                                      |
| Diastolic Blood Pressure (xxx)      | 72 mmHg                                   |
| Diastolic Blood Pressure units      | MMHG                                      |



US3902021

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 30 Mar 2021 18:11:35

Generated On: 10 Jun 2021 10:17:24

|                                     |   |
|-------------------------------------|---|
| Timepoint                           | Pre-Dose <input type="checkbox"/>             |
|                                     | Post-Dose <input checked="" type="checkbox"/> |
| Were vital signs assessed?          | Yes <input checked="" type="checkbox"/>       |
|                                     | No <input type="checkbox"/>                   |
| Date of assessment (dd MMM yyyy)    | 29 SEP 2020                                   |
| Time of assessment (00:00-23:59)    | 17:40 (24 HR)                                 |
| Vital Signs Date and Time (derived) | 29 SEP 2020 17:40                             |
| Temperature (xxx.x)                 | 97.3 F  |
| Route of measurement                | Oral <input checked="" type="checkbox"/>      |
|                                     | Axillary <input type="checkbox"/>             |
|                                     | Other <input type="checkbox"/>                |
| If Other, specify                   |   |
| Pulse (xxx)                         | 74 beats/min                                  |
| Pulse units                         | BPM   |
| Respiratory Rate (xxx)              | 16 breaths/min                                |
| Respiratory Rate units              | BREATHS/MIN                                   |
| Systolic Blood Pressure (xxx)       | 105 mmHg                                      |
| Systolic Blood Pressure units       | MMHG  |
| Diastolic Blood Pressure (xxx)      | 75 mmHg                                       |
| Diastolic Blood Pressure units      | MMHG  |

US3902021

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 30 Mar 2021 18:11:35

Generated On: 10 Jun 2021 10:17:24

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.*

US3902021

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Data signed: (b) (4) 30 Mar 2021 18:11:35

Generated On: 10 Jun 2021 10:17:24

|                                     |   |
|-------------------------------------|---|
| Was the pregnancy test performed?   | Yes <input checked="" type="radio"/>      |
|                                     | No <input type="radio"/>                  |
| Date of test ( <i>dd MMM yyyy</i> ) | 29 SEP 2020                               |
| Test performed                      | Urine <input checked="" type="radio"/>    |
|                                     | Serum <input type="radio"/>               |
| Result                              | Positive <input type="radio"/>            |
|                                     | Negative <input checked="" type="radio"/> |
| Was FSH sample collected?           | Yes <input type="radio"/>                 |
|                                     | No <input checked="" type="radio"/>       |
| Collection date                     |   |
| Collection time                     |   |
| Collection date and time (derived)  |   |

US3902021

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 30 Mar 2021 18:11:35

Generated On: 10 Jun 2021 10:17:24

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) 29 SEP 2020

What was the treatment time? (00:00-23:59) 17:09 (24 HR)

Treatment Date and Time (derived) 29 SEP 2020 17:09

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

US3902021

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 30 Mar 2021 18:11:35

Generated On: 10 Jun 2021 10:17:24

|                                    |                                      |
|------------------------------------|--------------------------------------|
| Was the sample collected?          | Yes <input checked="" type="radio"/> |
|                                    | No <input type="radio"/>             |
| Collection date (dd MMM yyyy)      | 29 SEP 2020                          |
| Collection time (00:00-23:59)      | 16:33 (24 HR)                        |
| Collection date and time (derived) | 29 SEP 2020 16:33                    |

US3902021

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 30 Mar 2021 18:10:56

Generated On: 10 Jun 2021 10:17:24

|                               |                           |                                 |                                    |
|-------------------------------|---------------------------|---------------------------------|------------------------------------|
| Collection date (dd MMM yyyy) |                           |                                 | 29 SEP 2020                        |
| Lab Test                      | Was the sample collected? | Collection time (00:00 - 23:59) | Collection date and time (derived) |
| Nasopharyngeal Swab 1         | Yes                       | 16:34                           | 29 SEP 2020 16:34                  |
| Nasopharyngeal Swab 2         | No                        |                                 |                                    |

US3902021

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 30 Mar 2021 18:11:35

Generated On: 10 Jun 2021 10:17:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3902021

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 10:17:24

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

29 SEP 2020 17:45

PC Open Date & Time

29 SEP 2020 17:29

PC Close Date & Time

29 SEP 2020 19:59



US3902021

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 10:17:24

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒  
No ☐

Please record your **TEMPERATURE** in °F

98.6 °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        | 29 SEP 2020 22:18 |
| PC Open Date & Time  | 29 SEP 2020 20:54 |
| PC Close Date & Time | 30 SEP 2020 11:59 |

US3902021

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 10:17:24

**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 <b>TEMPERATURE</b> taken?                            | Yes <input checked="" type="radio"/> |
|  | No <input type="radio"/>             |
| Please record your <b>TEMPERATURE</b> in °F              | 98.8 °F                              |
| Was any <b>MEDICATION TAKEN</b> today for pain or fever? | Yes <input checked="" type="radio"/> |
|  | No <input type="radio"/>             |

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

|   |       |
|---|-------|
| To <b>TREAT</b> pain or fever that has already occurred | True  |
| To <b>PREVENT</b> pain or fever from occurring          | False |

|                      |                   |
|----------------------|-------------------|
| PC Time Stamp        | 30 SEP 2020 15:27 |
| PC Open Date & Time  | 30 SEP 2020 12:00 |
| PC Close Date & Time | 01 OCT 2020 11:59 |

US3902021

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 10:17:24

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

02 OCT 2020 04:49

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3902021

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 10:17:24

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °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 OCT 2020 08:32

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3902021

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 10:17:24

**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 OCT 2020 08:26

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3902021

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 10:17:24

**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 OCT 2020 07:22

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3902021

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 10:17:24

**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

97.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

06 OCT 2020 08:39

PC Open Date & Time

05 OCT 2020 12:00

PC Close Date & Time

06 OCT 2020 11:59

US3902021

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 10:17:24

**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

29 SEP 2020 17:45

PC Open Date & Time

29 SEP 2020 17:29

PC Close Date & Time

29 SEP 2020 19:59



US3902021

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 10:17:24

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

Please select one response below

None ☐

Does not interfere with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☒

No ☐

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

5

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

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

Yes ☐

No ☒

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

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

29 SEP 2020 22:16

PC Open Date & Time

29 SEP 2020 20:54

PC Close Date & Time

30 SEP 2020 11:59

US3902021

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 10:17:24

**TIMEPOINT**

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☒

No ☐

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

5

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

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

Yes ☒

No ☐

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

90

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

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

30 SEP 2020 15:34

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3902021

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 10:17:24

**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 OCT 2020 04:49

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3902021

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 10:17:24

**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 OCT 2020 08:32

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3902021

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 10:17:24

**TIMEPOINT**

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

04 OCT 2020 08:27

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3902021

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 10:17:24

**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 OCT 2020 07:22

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3902021

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 10:17:24

**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

05 OCT 2020 21:09

PC Open Date & Time

05 OCT 2020 12:00

PC Close Date & Time

06 OCT 2020 11:59

US3902021

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 10:17:24

**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 ☐



US3902021

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 10:17:24

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

No ☒

Yes ☐

|                      |                   |
|----------------------|-------------------|
| PC Time stamp        | 29 SEP 2020 17:46 |
| PC Open Date & Time  | 29 SEP 2020 17:29 |
| PC Close Date & Time | 29 SEP 2020 19:59 |

US3902021

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 10:17:24

**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 ☐

US3902021

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 10:17:24

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

No ☒

Yes ☐

|                      |                   |
|----------------------|-------------------|
| PC Time stamp        | 29 SEP 2020 22:17 |
| PC Open Date & Time  | 29 SEP 2020 20:54 |
| PC Close Date & Time | 30 SEP 2020 11:59 |

US3902021

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 10:17:24

**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 ☒

US3902021

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 10:17:24

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 30 SEP 2020 15:35 |
| PC Open Date & Time          | 30 SEP 2020 12:00 |
| PC Close Date & Time         | 01 OCT 2020 11:59 |

US3902021

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 10:17:24

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 ☒

US3902021

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 10:17:24

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 02 OCT 2020 04:50 |
| PC Open Date & Time          | 01 OCT 2020 12:00 |
| PC Close Date & Time         | 02 OCT 2020 11:59 |

US3902021

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 10:17:24

**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 ☒



US3902021

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 10:17:24

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 03 OCT 2020 08:33 |
| PC Open Date & Time          | 02 OCT 2020 12:00 |
| PC Close Date & Time         | 03 OCT 2020 11:59 |

US3902021

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 10:17:24

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 ☒

US3902021

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 10:17:24

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 04 OCT 2020 08:27 |
| PC Open Date & Time          | 03 OCT 2020 12:00 |
| PC Close Date & Time         | 04 OCT 2020 11:59 |

US3902021

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 10:17:24

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 ☒

PRODUCTION RELEASE (v12.003

107 of 1879

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US3902021

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 10:17:24

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 05 OCT 2020 07:22 |
| PC Open Date & Time          | 04 OCT 2020 12:00 |
| PC Close Date & Time         | 05 OCT 2020 11:59 |

US3902021

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 10:17:24

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 ☒

US3902021

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 10:17:24

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 05 OCT 2020 21:09 |
| PC Open Date & Time          | 05 OCT 2020 12:00 |
| PC Close Date & Time         | 06 OCT 2020 11:59 |

US3902021

Folder: Diary Dose 2 (1)

Form: Headache\_Day(8)

Generated On: 10 Jun 2021 10:17:24

**TIMEPOINT**

DAY 8

Select one response below to indicate the intensity of your

**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 ☐

PC Time Stamp 07 OCT 2020 09:35

PC Open Date & Time 06 OCT 2020 12:00

PC Close Date & Time 07 OCT 2020 11:59



US3902021

Folder: Diary Dose 2 (1)

Form: Headache\_Day(9)

Generated On: 10 Jun 2021 10:17:24

**TIMEPOINT**

DAY 9

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 08 OCT 2020 00:47

PC Open Date & Time 07 OCT 2020 12:00

PC Close Date & Time 08 OCT 2020 11:59

US3902021

Folder: Diary Dose 2 (1)

Form: Headache\_Day(10)

Generated On: 10 Jun 2021 10:17:24

**TIMEPOINT**

DAY 10

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

08 OCT 2020 23:02

PC Open Date & Time

08 OCT 2020 12:00

PC Close Date & Time

09 OCT 2020 11:59

US3902021

Folder: Diary Dose 2 (1)

Form: Headache\_Day(11)

Generated On: 10 Jun 2021 10:17:24

**TIMEPOINT**

DAY 11

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

10 OCT 2020 07:25

PC Open Date & Time

09 OCT 2020 12:00

PC Close Date & Time

10 OCT 2020 11:59

US3902021

Folder: Diary Dose 2 (1)

Form: Headache\_Day(12)

Generated On: 10 Jun 2021 10:17:24

**TIMEPOINT**

DAY 12

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 11 OCT 2020 08:12

PC Open Date & Time 10 OCT 2020 12:00

PC Close Date & Time 11 OCT 2020 11:59

US3902021

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(8)

Generated On: 10 Jun 2021 10:17:24

|   |  |
|---|--|
| <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 OCT 2020 09:35  |
| PC Open Date & Time   | 06 OCT 2020 12:00  |
| PC Close Date & Time  | 07 OCT 2020 11:59  |

US3902021

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(9)

Generated On: 10 Jun 2021 10:17:24

|   |  |
|---|--|
| <b>TIMEPOINT</b>  | DAY 9  |
| Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms? | No <input checked="" type="radio"/><br>Yes <input type="radio"/> |
| PC Time stamp   | 08 OCT 2020 00:47  |
| PC Open Date & Time   | 07 OCT 2020 12:00  |
| PC Close Date & Time  | 08 OCT 2020 11:59  |

US3902021

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(10)

Generated On: 10 Jun 2021 10:17:24

|   |  |
|---|--|
| <b>TIMEPOINT</b>  | DAY 10   |
| Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms? | No <input checked="" type="radio"/><br>Yes <input type="radio"/> |
| PC Time stamp   | 08 OCT 2020 23:03  |
| PC Open Date & Time   | 08 OCT 2020 12:00  |
| PC Close Date & Time  | 09 OCT 2020 11:59  |

US3902021

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(11)

Generated On: 10 Jun 2021 10:17:24

TIMEPOINT

DAY 11

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

No ☒

Yes ☐

PC Time stamp

10 OCT 2020 07:25

PC Open Date & Time

09 OCT 2020 12:00

PC Close Date & Time

10 OCT 2020 11:59



US3902021

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(12)

Generated On: 10 Jun 2021 10:17:24

|   |  |
|---|--|
| <b>TIMEPOINT</b>  | DAY 12   |
| 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   | 11 OCT 2020 08:13  |
| PC Open Date & Time   | 10 OCT 2020 12:00  |
| PC Close Date & Time  | 11 OCT 2020 11:59  |

US3902021

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 30 Mar 2021 18:10:55

Generated On: 10 Jun 2021 10:17:24

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

7 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3902021

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 30 Mar 2021 18:10:55

Generated On: 10 Jun 2021 10:17:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3902021

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 30 Mar 2021 18:10:55

Generated On: 10 Jun 2021 10:17:24

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

13 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3902021

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 30 Mar 2021 18:10:55

Generated On: 10 Jun 2021 10:17:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3902021

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 30 Mar 2021 18:10:55

Generated On: 10 Jun 2021 10:17:24

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 22 OCT 2020

Please select one status for the follow-up contact  
Contact Made ☒  
Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3902021

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 30 Mar 2021 18:10:55

Generated On: 10 Jun 2021 10:17:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3902021

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 30 Mar 2021 18:11:36

Generated On: 10 Jun 2021 10:17:24

|   |   |
|---|---|
| Was this visit performed?                                       | Yes <input checked="" type="radio"/>    |
|   | No <input type="radio"/>                |
| Visit date (dd MMM yyyy)  | 27 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                                  |



US3902021

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 30 Mar 2021 18:11:36

Generated On: 10 Jun 2021 10:17:24

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) \_\_\_\_\_

US3902021

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 30 Mar 2021 18:11:36

Generated On: 10 Jun 2021 10:17:24

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.*

US3902021

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 30 Mar 2021 18:11:35

Generated On: 10 Jun 2021 10:17:24

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

|                               |             |
|-------------------------------|-------------|
| Collection date (dd MMM yyyy) | 27 OCT 2020 |
|-------------------------------|-------------|

|                               |               |
|-------------------------------|---------------|
| Collection time (00:00-23:59) | 14:44 (24 HR) |
|-------------------------------|---------------|

|                                    |                   |
|------------------------------------|-------------------|
| Collection date and time (derived) | 27 OCT 2020 14:44 |
|------------------------------------|-------------------|

US3902021

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 30 Mar 2021 18:11:35

Generated On: 10 Jun 2021 10:17:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3902021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:24

|   |  |
|---|--|
| <b>TIMEPOINT</b>  | DAY 64   |
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input checked="" type="radio"/><br>Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/><br>Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |  |
| Date and time of submission   | 02 NOV 2020 07:11:49   |
| Patient Cloud Open Date & Time  | 02 NOV 2020 00:01  |
| Patient Cloud Close Date & Time   | 06 NOV 2020 23:59  |

US3902021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:24

**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

09 NOV 2020 07:51:16

Patient Cloud Open Date & Time

09 NOV 2020 00:01

Patient Cloud Close Date & Time

13 NOV 2020 23:59

US3902021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:24

| TIMEPOINT   | DAY 78   |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input 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   | 16 NOV 2020 14:53:13   |
| Patient Cloud Open Date & Time  | 16 NOV 2020 00:01  |
| Patient Cloud Close Date & Time   | 20 NOV 2020 23:59  |

US3902021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:24

| TIMEPOINT   | DAY 82  |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |   |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )  | <input type="checkbox"/>  |
| Chills  | <input type="checkbox"/>  |
| Cough   | <input type="checkbox"/>  |
| Shortness of breath   | <input type="checkbox"/>  |
| Difficulty breathing  | <input type="checkbox"/>  |
| Fatigue   | <input type="checkbox"/>  |
| Muscle aches  | <input type="checkbox"/>  |
| Body aches  | <input type="checkbox"/>  |
| Headache  | <input type="checkbox"/>  |
| New loss of taste   | <input type="checkbox"/>  |
| New loss of smell   | <input type="checkbox"/>  |
| Sore throat   | <input type="checkbox"/>  |
| Congestion  | <input type="checkbox"/>  |
| Runny nose  | <input type="checkbox"/>  |
| Nausea  | <input type="checkbox"/>  |
| Vomiting  | <input type="checkbox"/>  |
| Diarrhea  | <input type="checkbox"/>  |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="radio"/><br>Yes <input type="radio"/>   |



**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

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

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[Patient Cloud Open Date & Time](#)

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20 NOV 2020 00:01

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[Patient Cloud Close Date & Time](#)

---

24 NOV 2020 23:59

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US3902021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:24

**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 ☒

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

30 NOV 2020 00:04:26

Patient Cloud Open Date & Time

27 NOV 2020 00:01

Patient Cloud Close Date & Time

01 DEC 2020 23:59

US3902021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:24

| 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 07:23:03   |
| Patient Cloud Open Date & Time  | 04 DEC 2020 00:01  |
| Patient Cloud Close Date & Time   | 08 DEC 2020 23:59  |

US3902021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:24

**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

11 DEC 2020 11:02:29

Patient Cloud Open Date & Time

11 DEC 2020 00:01

Patient Cloud Close Date & Time

15 DEC 2020 23:59

US3902021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:24

| TIMEPOINT   | DAY 110  |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input checked="" type="radio"/><br>Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/><br>Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |  |
| Date and time of submission   | 18 DEC 2020 07:40:49   |
| Patient Cloud Open Date & Time  | 18 DEC 2020 00:01  |
| Patient Cloud Close Date & Time   | 22 DEC 2020 23:59  |

US3902021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:24

**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 09:00:41

Patient Cloud Open Date & Time

25 DEC 2020 00:01

Patient Cloud Close Date & Time

29 DEC 2020 23:59

US3902021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:24

**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

02 JAN 2021 08:23:20

Patient Cloud Open Date & Time

01 JAN 2021 00:01

Patient Cloud Close Date & Time

05 JAN 2021 23:59

US3902021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:24

**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

08 JAN 2021 16:11:02

Patient Cloud Open Date & Time

08 JAN 2021 00:01

Patient Cloud Close Date & Time

12 JAN 2021 23:59



US3902021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:24

**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 ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

15 JAN 2021 07:54:26

Patient Cloud Open Date & Time

15 JAN 2021 00:01

Patient Cloud Close Date & Time

19 JAN 2021 23:59

US3902021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:24

**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 14:08:04

Patient Cloud Open Date & Time

22 JAN 2021 00:01

Patient Cloud Close Date & Time

26 JAN 2021 23:59

US3902021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:24

**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

02 FEB 2021 15:48:19

Patient Cloud Open Date & Time

29 JAN 2021 00:01

Patient Cloud Close Date & Time

02 FEB 2021 23:59

US3902021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:24

**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 23:47:37

Patient Cloud Open Date & Time

05 FEB 2021 00:01

Patient Cloud Close Date & Time

09 FEB 2021 23:59

US3902021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:24

**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

12 FEB 2021 12:46:01

Patient Cloud Open Date & Time

12 FEB 2021 00:01

Patient Cloud Close Date & Time

16 FEB 2021 23:59

US3902021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:24

| TIMEPOINT   | DAY 173  |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="radio"/><br>Yes <input 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   | 19 FEB 2021 15:46:14   |
| Patient Cloud Open Date & Time  | 19 FEB 2021 00:01  |
| Patient Cloud Close Date & Time   | 23 FEB 2021 23:59  |

US3902021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:24

**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

28 FEB 2021 19:02:00

Patient Cloud Open Date & Time

26 FEB 2021 00:01

Patient Cloud Close Date & Time

02 MAR 2021 23:59

US3902021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:24

**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

09 MAR 2021 08:51:20

Patient Cloud Open Date & Time

05 MAR 2021 00:01

Patient Cloud Close Date & Time

09 MAR 2021 23:59



US3902021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:24

|   |  |
|---|--|
| <b>TIMEPOINT</b>  | DAY 194  |
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input 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   | 12 MAR 2021 06:51:34   |
| Patient Cloud Open Date & Time  | 12 MAR 2021 00:01  |
| Patient Cloud Close Date & Time   | 16 MAR 2021 23:59  |

US3902021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:24

|   |  |
|---|--|
| <b>TIMEPOINT</b>  | 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 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   | 19 MAR 2021 11:10:03   |
| Patient Cloud Open Date & Time  | 19 MAR 2021 00:01  |
| Patient Cloud Close Date & Time   | 23 MAR 2021 23:59  |

US3902021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:24

**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 09:41:30

Patient Cloud Open Date & Time

26 MAR 2021 00:01

Patient Cloud Close Date & Time

30 MAR 2021 23:59

US3902021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:24

**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 ☒

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

03 APR 2021 11:10:50

Patient Cloud Open Date & Time

02 APR 2021 00:01

Patient Cloud Close Date & Time

06 APR 2021 23:59

US3902021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:24

**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

09 APR 2021 09:37:27

Patient Cloud Open Date & Time

09 APR 2021 00:01

Patient Cloud Close Date & Time

13 APR 2021 23:59

US3902021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:24

**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

16 APR 2021 07:25:43

Patient Cloud Open Date & Time

16 APR 2021 00:01

Patient Cloud Close Date & Time

20 APR 2021 23:59

US3902021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:24

**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 ☒

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

23 APR 2021 07:03:44

Patient Cloud Open Date & Time

23 APR 2021 00:01

Patient Cloud Close Date & Time

27 APR 2021 23:59

US3902021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:24

**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

30 APR 2021 21:50:01

Patient Cloud Open Date & Time

30 APR 2021 00:01

Patient Cloud Close Date & Time

04 MAY 2021 23:59



US3902021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:24

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

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

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

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[Patient Cloud Close Date & Time](#)

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11 MAY 2021 23:59

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US3902021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:24

**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°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 ☐

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

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

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[Patient Cloud Close Date & Time](#)

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18 MAY 2021 23:59

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US3902021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:24

| 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"/>  |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

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

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[Patient Cloud Close Date & Time](#)

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25 MAY 2021 23:59

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US3902021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:24

**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 ☐

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

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

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[Patient Cloud Close Date & Time](#)

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01 JUN 2021 23:59

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US3902021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:24

**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 ☐  
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 ☐

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and 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](#)

04 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

08 JUN 2021 23:59

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US3902021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:24

**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 ☐  
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 ☐

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and 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>  | 11 JUN 2021 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 15 JUN 2021 23:59 |

US3902021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:24

| TIMEPOINT   | DAY 292  |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="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"/>  |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and 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>  | 18 JUN 2021 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 22 JUN 2021 23:59 |

US3902021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:24

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

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and 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>  | 25 JUN 2021 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 29 JUN 2021 23:59 |



US3902021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:24

**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 ☐

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

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

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[Patient Cloud Close Date & Time](#)

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06 JUL 2021 23:59

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US3902021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:24

**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 ☐

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

13 JUL 2021 23:59

US3902021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:24

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

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

20 JUL 2021 23:59

US3902021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:24

**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 ☐

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

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

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[Patient Cloud Close Date & Time](#)

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27 JUL 2021 23:59

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US3902021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:24

| 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"/>  |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

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

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[Patient Cloud Close Date & Time](#)

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03 AUG 2021 23:59

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US3902021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:24

| 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"/>   |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

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

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[Patient Cloud Close Date & Time](#)

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10 AUG 2021 23:59

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US3902021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:24

| 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°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"/>  |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and 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>  | 13 AUG 2021 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 17 AUG 2021 23:59 |

US3902021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:24

**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 ☐

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

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

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[Patient Cloud Close Date & Time](#)

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24 AUG 2021 23:59

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US3902021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:24

| TIMEPOINT   | DAY 362   |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |   |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )  | <input type="checkbox"/>  |
| Chills  | <input type="checkbox"/>  |
| Cough   | <input type="checkbox"/>  |
| Shortness of breath   | <input type="checkbox"/>  |
| Difficulty breathing  | <input type="checkbox"/>  |
| Fatigue   | <input type="checkbox"/>  |
| Muscle aches  | <input type="checkbox"/>  |
| Body aches  | <input type="checkbox"/>  |
| Headache  | <input type="checkbox"/>  |
| New loss of taste   | <input type="checkbox"/>  |
| New loss of smell   | <input type="checkbox"/>  |
| Sore throat   | <input type="checkbox"/>  |
| Congestion  | <input type="checkbox"/>  |
| Runny nose  | <input type="checkbox"/>  |
| Nausea  | <input type="checkbox"/>  |
| Vomiting  | <input type="checkbox"/>  |
| Diarrhea  | <input type="checkbox"/>  |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="radio"/><br>Yes <input type="radio"/>   |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and 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>  | 27 AUG 2021 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 31 AUG 2021 23:59 |

US3902021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:24

**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 ☐

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and 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](#)

03 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

07 SEP 2021 23:59

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US3902021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:24

**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 ☐

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and 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>  | 10 SEP 2021 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 14 SEP 2021 23:59 |

US3902021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:24

**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 ☐

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and 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](#)

17 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

21 SEP 2021 23:59

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US3902021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:24

| TIMEPOINT   | DAY 390  |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="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"/>  |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and 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](#)

24 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

28 SEP 2021 23:59

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US3902021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:24

**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 ☐

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and 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>  | 01 OCT 2021 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 05 OCT 2021 23:59 |

US3902021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:24

| 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"/>  |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

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

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[Patient Cloud Close Date & Time](#)

12 OCT 2021 23:59

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US3902021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:24

| 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"/>   |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 OCT 2021 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 19 OCT 2021 23:59 |



US3902021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:24

**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 ☐

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 OCT 2021 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 26 OCT 2021 23:59 |

US3902021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:24

**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 ☐

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

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

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[Patient Cloud Close Date & Time](#)

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02 NOV 2021 23:59

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US3902021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:24

**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°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 ☐

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

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

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[Patient Cloud Close Date & Time](#)

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09 NOV 2021 23:59

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US3902021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:24

| TIMEPOINT   | DAY 439  |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="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"/>  |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

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

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[Patient Cloud Close Date & Time](#)

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16 NOV 2021 23:59

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US3902021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:24

| 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"/>  |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

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

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[Patient Cloud Close Date & Time](#)

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23 NOV 2021 23:59

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US3902021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:24

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

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and 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>  | 26 NOV 2021 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 30 NOV 2021 23:59 |

US3902021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:24

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

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

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

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[Patient Cloud Close Date & Time](#)

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07 DEC 2021 23:59

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US3902021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:24

**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 ☐  
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 ☐

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and 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>  | 10 DEC 2021 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 14 DEC 2021 23:59 |



US3902021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:24

**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 ☐

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

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

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[Patient Cloud Close Date & Time](#)

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21 DEC 2021 23:59

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US3902021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:24

**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 ☐  
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 ☐

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and 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>  | 24 DEC 2021 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 28 DEC 2021 23:59 |

US3902021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:24

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

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

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

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[Patient Cloud Close Date & Time](#)

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04 JAN 2022 23:59

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US3902021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:24

| 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"/>  |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

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

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[Patient Cloud Close Date & Time](#)

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11 JAN 2022 23:59

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US3902021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:24

**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 ☐

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

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

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[Patient Cloud Close Date & Time](#)

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18 JAN 2022 23:59

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US3902021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:24

**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 ☐

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

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

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[Patient Cloud Close Date & Time](#)

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25 JAN 2022 23:59

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US3902021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:24

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

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

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

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[Patient Cloud Close Date & Time](#)

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01 FEB 2022 23:59

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US3902021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:24

**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 ☐

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and 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](#)

04 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

08 FEB 2022 23:59

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US3902021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:24

| 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"/>  |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and 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>  | 11 FEB 2022 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 15 FEB 2022 23:59 |

US3902021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:24

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 ☐

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

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

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[Patient Cloud Close Date & Time](#)

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22 FEB 2022 23:59

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US3902021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:24

**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 ☐ 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 ☐

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

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

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[Patient Cloud Close Date & Time](#)

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01 MAR 2022 23:59

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US3902021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:24

**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 ☐

**US3902021**

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

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**Generated On: 10 Jun 2021 10:17:24**

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

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[Patient Cloud Close Date & Time](#)

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08 MAR 2022 23:59

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US3902021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:24

**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 ☐

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

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

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[Patient Cloud Close Date & Time](#)

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15 MAR 2022 23:59

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US3902021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:24

**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 ☐

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and 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>  | 18 MAR 2022 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 22 MAR 2022 23:59 |

US3902021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:24

**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 ☐

**US3902021**

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

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**Generated On: 10 Jun 2021 10:17:24**

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

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[Patient Cloud Close Date & Time](#)

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29 MAR 2022 23:59

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US3902021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:24

**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 ☐

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

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

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[Patient Cloud Close Date & Time](#)

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05 APR 2022 23:59

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US3902021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:24

**TIMEPOINT**

DAY 586

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and 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>  | 08 APR 2022 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 12 APR 2022 23:59 |

US3902021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:24

**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 ☐

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 APR 2022 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 19 APR 2022 23:59 |

US3902021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:24

| 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"/>  |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 APR 2022 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 26 APR 2022 23:59 |

US3902021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:24

| 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"/>  |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

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

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[Patient Cloud Close Date & Time](#)

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03 MAY 2022 23:59

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US3902021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:24

| 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"/>  |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

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

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[Patient Cloud Close Date & Time](#)

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10 MAY 2022 23:59

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US3902021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:24

| 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"/>  |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and 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](#)

13 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

17 MAY 2022 23:59

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US3902021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:24

**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 ☐

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and 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](#)

20 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

24 MAY 2022 23:59

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US3902021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:24

**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 ☐

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

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

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[Patient Cloud Close Date & Time](#)

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31 MAY 2022 23:59

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US3902021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:24

**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 ☐ 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 ☐

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and 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>  | 03 JUN 2022 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 07 JUN 2022 23:59 |

US3902021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:24

| TIMEPOINT   | DAY 649   |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |   |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )  | <input type="checkbox"/>  |
| Chills  | <input type="checkbox"/>  |
| Cough   | <input type="checkbox"/>  |
| Shortness of breath   | <input type="checkbox"/>  |
| Difficulty breathing  | <input type="checkbox"/>  |
| Fatigue   | <input type="checkbox"/>  |
| Muscle aches  | <input type="checkbox"/>  |
| Body aches  | <input type="checkbox"/>  |
| Headache  | <input type="checkbox"/>  |
| New loss of taste   | <input type="checkbox"/>  |
| New loss of smell   | <input type="checkbox"/>  |
| Sore throat   | <input type="checkbox"/>  |
| Congestion  | <input type="checkbox"/>  |
| Runny nose  | <input type="checkbox"/>  |
| Nausea  | <input type="checkbox"/>  |
| Vomiting  | <input type="checkbox"/>  |
| Diarrhea  | <input type="checkbox"/>  |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="radio"/><br>Yes <input type="radio"/>   |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and 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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10 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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14 JUN 2022 23:59

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US3902021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:24

**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 ☐

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and 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>  | 17 JUN 2022 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 21 JUN 2022 23:59 |

US3902021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:24

**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 ☐

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and 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>  | 24 JUN 2022 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 28 JUN 2022 23:59 |



US3902021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:24

| 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"/>  |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and 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>  | 01 JUL 2022 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 05 JUL 2022 23:59 |

US3902021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:24

**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°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 ☐

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

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

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[Patient Cloud Close Date & Time](#)

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12 JUL 2022 23:59

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US3902021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:24

| 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"/>  |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 JUL 2022 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 19 JUL 2022 23:59 |

US3902021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:24

| 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"/>  |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 JUL 2022 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 26 JUL 2022 23:59 |



US3902021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:24

**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 ☐

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

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

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[Patient Cloud Close Date & Time](#)

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02 AUG 2022 23:59

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US3902021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:24

**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 ☐

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

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

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[Patient Cloud Close Date & Time](#)

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09 AUG 2022 23:59

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US3902021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:24

| TIMEPOINT   | DAY 712   |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |   |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )  | <input type="checkbox"/>  |
| Chills  | <input type="checkbox"/>  |
| Cough   | <input type="checkbox"/>  |
| Shortness of breath   | <input type="checkbox"/>  |
| Difficulty breathing  | <input type="checkbox"/>  |
| Fatigue   | <input type="checkbox"/>  |
| Muscle aches  | <input type="checkbox"/>  |
| Body aches  | <input type="checkbox"/>  |
| Headache  | <input type="checkbox"/>  |
| New loss of taste   | <input type="checkbox"/>  |
| New loss of smell   | <input type="checkbox"/>  |
| Sore throat   | <input type="checkbox"/>  |
| Congestion  | <input type="checkbox"/>  |
| Runny nose  | <input type="checkbox"/>  |
| Nausea  | <input type="checkbox"/>  |
| Vomiting  | <input type="checkbox"/>  |
| Diarrhea  | <input type="checkbox"/>  |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="radio"/><br>Yes <input type="radio"/>   |

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

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

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[Patient Cloud Close Date & Time](#)

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16 AUG 2022 23:59

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US3902021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:24

| TIMEPOINT   | DAY 719  |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="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"/>  |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and 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>  | 19 AUG 2022 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 23 AUG 2022 23:59 |



US3902021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:24

| TIMEPOINT   | DAY 726   |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |   |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )  | <input type="checkbox"/>  |
| Chills  | <input type="checkbox"/>  |
| Cough   | <input type="checkbox"/>  |
| Shortness of breath   | <input type="checkbox"/>  |
| Difficulty breathing  | <input type="checkbox"/>  |
| Fatigue   | <input type="checkbox"/>  |
| Muscle aches  | <input type="checkbox"/>  |
| Body aches  | <input type="checkbox"/>  |
| Headache  | <input type="checkbox"/>  |
| New loss of taste   | <input type="checkbox"/>  |
| New loss of smell   | <input type="checkbox"/>  |
| Sore throat   | <input type="checkbox"/>  |
| Congestion  | <input type="checkbox"/>  |
| Runny nose  | <input type="checkbox"/>  |
| Nausea  | <input type="checkbox"/>  |
| Vomiting  | <input type="checkbox"/>  |
| Diarrhea  | <input type="checkbox"/>  |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="radio"/><br>Yes <input type="radio"/>   |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and 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>  | 26 AUG 2022 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 30 AUG 2022 23:59 |

US3902021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:24

| 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"/>  |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

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

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[Patient Cloud Close Date & Time](#)

06 SEP 2022 23:59

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US3902021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:24

| TIMEPOINT   | DAY 740   |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |   |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )  | <input type="checkbox"/>  |
| Chills  | <input type="checkbox"/>  |
| Cough   | <input type="checkbox"/>  |
| Shortness of breath   | <input type="checkbox"/>  |
| Difficulty breathing  | <input type="checkbox"/>  |
| Fatigue   | <input type="checkbox"/>  |
| Muscle aches  | <input type="checkbox"/>  |
| Body aches  | <input type="checkbox"/>  |
| Headache  | <input type="checkbox"/>  |
| New loss of taste   | <input type="checkbox"/>  |
| New loss of smell   | <input type="checkbox"/>  |
| Sore throat   | <input type="checkbox"/>  |
| Congestion  | <input type="checkbox"/>  |
| Runny nose  | <input type="checkbox"/>  |
| Nausea  | <input type="checkbox"/>  |
| Vomiting  | <input type="checkbox"/>  |
| Diarrhea  | <input type="checkbox"/>  |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="radio"/><br>Yes <input type="radio"/>   |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and 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>  | 09 SEP 2022 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 13 SEP 2022 23:59 |

US3902021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:24

| 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"/>  |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and 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>  | 16 SEP 2022 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 20 SEP 2022 23:59 |



US3902021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:24

| 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"/>   |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and 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>  | 23 SEP 2022 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 27 SEP 2022 23:59 |

US3902021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:24

**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 ☐  
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 ☐

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and 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>  | 30 SEP 2022 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 04 OCT 2022 23:59 |

US3902021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:24

| TIMEPOINT   | DAY 768  |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="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"/>  |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and 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>  | 07 OCT 2022 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 11 OCT 2022 23:59 |

US3902021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:24

**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 ☐

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 OCT 2022 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 18 OCT 2022 23:59 |



US3902021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:24

**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 ☐

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 OCT 2022 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 25 OCT 2022 23:59 |

US3902021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:24

**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 ☐

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

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

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[Patient Cloud Close Date & Time](#)

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01 NOV 2022 23:59

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US3902021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:24

| 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"/>  |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

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

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[Patient Cloud Close Date & Time](#)

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08 NOV 2022 23:59

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US3902021

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary

Generated On: 10 Jun 2021 10:17:24

| 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  |  | 28 FEB 2021 19:02:12      |

US3902021

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 30 Mar 2021 18:10:55

Generated On: 10 Jun 2021 10:17:24

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*



US3902021

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 30 Mar 2021 18:10:55

Generated On: 10 Jun 2021 10:17:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3902021

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 30 Mar 2021 18:10:55

Generated On: 10 Jun 2021 10:17:24

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

28 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3902021

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 30 Mar 2021 18:10:55

Generated On: 10 Jun 2021 10:17:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3902021

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 30 Mar 2021 18:10:55

Generated On: 10 Jun 2021 10:17:24

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

29 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3902021

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 30 Mar 2021 18:10:55

Generated On: 10 Jun 2021 10:17:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3902021

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 30 Mar 2021 18:10:55

Generated On: 10 Jun 2021 10:17:24

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 25 FEB 2021

Please select one status for the follow-up contact  
Contact Made ☒  
Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3902021

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 30 Mar 2021 18:10:55

Generated On: 10 Jun 2021 10:17:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3902021

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 30 Mar 2021 18:11:36

Generated On: 10 Jun 2021 10:17:24

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



US3902021

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 16 Apr 2021 20:42:13

Generated On: 10 Jun 2021 10:17:24

|                                     |                                       |
|-------------------------------------|---------------------------------------|
| Were vital signs assessed?          | Yes <input checked="" type="radio"/>  |
|                                     | No <input type="radio"/>              |
| Date of assessment (dd MMM yyyy)    | 25 MAR 2021                           |
| Time of assessment (00:00-23:59)    | 14:18 (24 HR)                         |
| Vital Signs Date and Time (derived) | 25 MAR 2021 14:18                     |
| Temperature (xxx.x)                 | 98.8 F                                |
| Route of measurement                | Oral <input checked="" type="radio"/> |
|                                     | Axillary <input type="radio"/>        |
|                                     | Other <input type="radio"/>           |
| If Other, specify                   |                                       |
| Pulse (xxx)                         | 73 beats/min                          |
| Pulse units                         | BPM                                   |
| Respiratory Rate (xxx)              | 16 breaths/min                        |
| Respiratory Rate units              | BREATHS/MIN                           |
| Systolic Blood Pressure (xxx)       | 103 mmHg                              |
| Systolic Blood Pressure units       | MMHG                                  |
| Diastolic Blood Pressure (xxx)      | 70 mmHg                               |
| Diastolic Blood Pressure units      | MMHG                                  |
| Height (derived)                    |                                       |
| Weight (derived)                    |                                       |

US3902021

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 30 Mar 2021 18:11:36

Generated On: 10 Jun 2021 10:17:24

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.*

US3902021

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 30 Mar 2021 18:11:36

Generated On: 10 Jun 2021 10:17:24

|                           |                                      |
|---------------------------|--------------------------------------|
| 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) | 14:46 (24 HR) |
|-------------------------------|---------------|

|                                    |                   |
|------------------------------------|-------------------|
| Collection date and time (derived) | 25 MAR 2021 14:46 |
|------------------------------------|-------------------|

US3902021

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 30 Mar 2021 18:11:36

Generated On: 10 Jun 2021 10:17:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

**US3902021**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 10:17:24**

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*

**US3902021**

**Folder: Safety Call Day 239 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 10:17:24**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

**US3902021**

**Folder: Covid-19 Assessment (1)**

**Form: COVID-19 Contact**

**Generated On: 10 Jun 2021 10:17:24**

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

**US3902021**

**Folder: Covid-19 Assessment (1)**

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

**Generated On: 10 Jun 2021 10:17:24**

---

Generate Next COVID-19 Assessment

Yes ☐

No ☐

---



US3902021

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

Form: Visit Date

Data signed: (b) (4) 30 Mar 2021 18:10:54

Generated On: 10 Jun 2021 10:17:24

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

|                          |             |
|--------------------------|-------------|
| Visit date (dd MMM yyyy) | 10 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 | UNBLND_DECIDE |
|------------|---------------|

US3902021

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

Form: Unblinding

Data signed: (b) (4) 30 Mar 2021 18:10:54

Generated On: 10 Jun 2021 10:17:24

Date of updated informed consent (dd MMM yyyy) 10 MAR 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) 10 MAR 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 \_\_\_\_\_

US3902021

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Apr 2021 20:42:13

Generated On: 10 Jun 2021 10:17:24

|                                    |                                      |
|------------------------------------|--------------------------------------|
| Was the sample collected?          | Yes <input checked="" type="radio"/> |
|                                    | No <input type="radio"/>             |
| Collection date (dd MMM yyyy)      | 10 MAR 2021                          |
| Collection time (00:00-23:59)      | 12:42 (24 HR)                        |
| Collection date and time (derived) | 10 MAR 2021 12:42                    |

US3902021

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 30 Mar 2021 18:10:54

Generated On: 10 Jun 2021 10:17:24

Was the sample collected? Yes ☒  
No ☐

Collection date (dd MMM yyyy) 10 MAR 2021

Collection time (00:00 - 23:59) 12:43

Collection Date and Time (derived) 10 MAR 2021 12:43

US3902021

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 23 Apr 2021 17:08:48

Generated On: 10 Jun 2021 10:17:24

---

Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

---

US3902021

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:17:24

|  |  |
|--|--|
| AEID   | USA-US210-2021-MRNA-1273-P30<br>1000002  |
| Adverse event  | CHOLELITHIASIS   |
| 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)                                       | 22 FEB 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)                         | 1 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)                          | 22 FEB 2021  |
| Hospital Discharge Date (dd MMM yyyy)                          | 25 FEB 2021  |
| Admitted to ICU?   | Yes <input type="radio"/><br>No <input checked="" type="radio"/><br>Unknown <input type="radio"/>  |
| Number of Days in ICU  |  |

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EAB) (1725)

341 of 1879

US3902021

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:17:24

|  |   |
|--|---|
| Persistent or significant disability or incapacity                           | False   |
| Congenital anomaly or birth defect   | False   |
| Other medically important event  | False   |
| Relationship to investigational product                                      | Not Related <input checked="" type="radio"/><br>Related <input type="radio"/><br>Not Applicable <input type="radio"/>   |
| Relationship to Study Procedure  | Not Related <input checked="" type="radio"/><br>Related <input type="radio"/><br>Not Applicable <input type="radio"/>   |
| Action taken with investigational product                                    | None <input type="radio"/><br>Dose Delayed <input type="radio"/><br>Investigational Product <input type="radio"/><br>Withdrawn <input type="radio"/><br>Not Applicable <input checked="" type="radio"/>   |
| Other action taken (check all that apply)                                    |   |
| None   | False   |
| Concomitant Medication   | True  |
| Concomitant Procedure  | True  |
| Outcome  | Fatal <input type="radio"/><br>Not Recovered/Not Resolved <input type="radio"/><br>Recovered/Resolved <input 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  |   |

US3902021

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:17:24

---

PER CRC SOURCE NOTES:  
DURING DAY 179 SAFETY  
PHONE CONTACT SUBJECT  
STATED SHE WENT TO HOLMES  
REGIONAL ER WITH RIGHT SIDE  
SHOULDER AND BELLY PAIN;  
DIAGNOSED WITH  
CHOLELITHIASIS ON 02/22/2021.  
A CHOLECYSTECTOMY WAS  
PERFORMED ON 02/23/2021.  
SUBJECT DISCHARGED ON  
02/25/2021 WITH A PAIN MED  
AND AN ANTIBIOTIC. SUBJECT  
STATES SHE IS FEELING  
BETTER.

---

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

---



US3902021

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:17:24

AEID

Adverse event

ARTHRALGIA

Was this a medically-attended AE?

Yes ☐

No ☒

Was this a Solicited Adverse Reaction?

Yes ☒

No ☐

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Yes ☐

No ☒

Start date (dd MMM yyyy)

11 SEP 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

11 SEP 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

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 ☐

No ☐

Unknown ☐

Number of Days in ICU

Persistent or significant disability or incapacity

False

PRODUCTION RELEASE (v12.003

EAB) (1725)

344 of 1879

US3902021

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:17:24

|  |   |
|--|---|
| Congenital anomaly or birth defect   | False   |
| Other medically important event  | False   |
| Relationship to investigational product                                      | Not Related <input type="radio"/><br>Related <input checked="" type="radio"/><br>Not Applicable <input type="radio"/>   |
| Relationship to Study Procedure  | Not Related <input checked="" type="radio"/><br>Related <input type="radio"/><br>Not Applicable <input type="radio"/>   |
| Action taken with investigational product                                    | None <input checked="" type="radio"/><br>Dose Delayed <input type="radio"/><br>Investigational Product Withdrawn <input type="radio"/><br>Not Applicable <input type="radio"/>  |
| Other action taken (check all that apply)                                    |   |
| None   | True  |
| Concomitant Medication   | False   |
| Concomitant Procedure  | False   |
| Outcome  | Fatal <input type="radio"/><br>Not Recovered/Not Resolved <input type="radio"/><br>Recovered/Resolved <input checked="" type="radio"/><br>Recovered/Resolved with Sequelae <input type="radio"/><br>Recovering/Resolving <input type="radio"/><br>Unknown <input type="radio"/> |
| If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: |   |
| Narrative  |   |
| Serious Adverse Event Derived (CSA Programming Field Only)                   | 0   |
| Medically Attended AE Derived (CSA Programming Field Only)                   | 0   |
| Admitted to ICU Derived (CSA Programming Field Only)                         |   |

US3902021

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:17:24

AEID

Adverse event

ONGOING HEADACHE

Was this a medically-attended AE?

Yes ☐

No ☒

Was this a Solicited Adverse Reaction?

Yes ☒

No ☐

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Yes ☐

No ☒

Start date (dd MMM yyyy)

07 OCT 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

10 OCT 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

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 ☐

No ☐

Unknown ☐

Number of Days in ICU

Persistent or significant disability or incapacity

False

PRODUCTION RELEASE (v12.003

346 of 1879

EAB) (1725)

US3902021

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:17:24

|   |   |
|---|---|
| Congenital anomaly or birth defect  | False   |
| Other medically important event   | False   |
| Relationship to investigational product   | Not Related <input type="radio"/><br>Related <input checked="" type="radio"/><br>Not Applicable <input type="radio"/>   |
| Relationship to Study Procedure   | Not Related <input checked="" type="radio"/><br>Related <input type="radio"/><br>Not Applicable <input type="radio"/>   |
| Action taken with investigational product   | None <input checked="" type="radio"/><br>Dose Delayed <input type="radio"/><br>Investigational Product Withdrawn <input type="radio"/><br>Not Applicable <input type="radio"/>  |
| Other action taken (check all that apply)   |   |
| None  | True  |
| Concomitant Medication  | False   |
| Concomitant Procedure   | False   |
| Outcome   | Fatal <input type="radio"/><br>Not Recovered/Not Resolved <input type="radio"/><br>Recovered/Resolved <input checked="" type="radio"/><br>Recovered/Resolved with Sequelae <input type="radio"/><br>Recovering/Resolving <input type="radio"/><br>Unknown <input type="radio"/> |
| If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:<br>_____ |   |
| Narrative<br>_____  |   |
| Serious Adverse Event Derived (CSA Programming Field Only)                            | 0   |
| Medically Attended AE Derived (CSA Programming Field Only)                            | 0   |
| Admitted to ICU Derived (CSA Programming Field Only)                                  | _____   |

US3902021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 30 Mar 2021 18:10:54

Generated On: 10 Jun 2021 10:17:24

---

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

Yes ☒

No ☐

---

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

---

US3902021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 30 Mar 2021 18:10:54

Generated On: 10 Jun 2021 10:17:24

Name of Medication IBUPROFEN

Prophylaxis Yes ☐  
No ☒

Indication 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 ☐  
Intraocular ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

349 of 1879

US3902021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 30 Mar 2021 18:10:54

Generated On: 10 Jun 2021 10:17:24

|  |                          |                                     |
|--|--------------------------|-------------------------------------|
|  | 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)                           |                          | 30 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)             |                          | 10 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"/>            |

US3902021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 30 Mar 2021 18:10:54

Generated On: 10 Jun 2021 10:17:24

Name of Medication OXYCODONE/ACETAMINOPHE  
N

Prophylaxis Yes ☐  
No ☒

Indication CHOLELITHIASIS

Dose per administration 5/325

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)

351 of 1879



US3902021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 30 Mar 2021 18:10:54

Generated On: 10 Jun 2021 10:17:24

|  |                          |                                  |
|--|--------------------------|----------------------------------|
|  | 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)                       | 25 FEB 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)               |                          |                                  |
| Interval Dosage Unit Number (derived)          |                          |                                  |
| Interval Dosage Definition (derived)           | 802                      | <input type="radio"/>            |
|  | 803                      | <input type="radio"/>            |
|  | 804                      | <input type="radio"/>            |

US3902021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 30 Mar 2021 18:10:54

Generated On: 10 Jun 2021 10:17:24

Name of Medication AMOXICILLIN/POTASSIUM  
CLAVULANATE (AUGMENTIN)

Prophylaxis Yes ☐  
No ☒

Indication CHOLELITHIASIS

Dose per administration 875/125

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)

353 of 1879

US3902021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 30 Mar 2021 18:10:54

Generated On: 10 Jun 2021 10:17:24

|  |                          |                                  |
|--|--------------------------|----------------------------------|
|  | 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)                           |                          | 25 FEB 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)                   |                          | 2                                |
| Interval Dosage Unit Number (derived)              |                          | 1                                |
| Interval Dosage Definition (derived)               | 802                      | <input type="radio"/>            |
|  | 803                      | <input type="radio"/>            |
|  | 804                      | <input checked="" type="radio"/> |

US3902021

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 30 Mar 2021 18:10:54

Generated On: 10 Jun 2021 10:17:24

---

Were any concomitant procedures performed?

Yes ☒

No ☐

---

If yes, please complete Concomitant Procedures form.

---

US3902021

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 30 Mar 2021 18:10:54

Generated On: 10 Jun 2021 10:17:24

| Procedure/Surgery date (dd MMM<br>yyyy) | Procedure/Surgery | Indication    | If indication is Other, specify |
|---|-------------------|---------------|---------------------------------|
| 23 FEB 2021                             | CHOLECYSTECTOMY   | Adverse Event |                                 |

US3902021

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 10:17:24

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 ☐

US3902021

Folder: SAE USA-US210-2021-MRNA-1273-P301000002

Form: Safety Report Form

Data signed: (b) (4) 30 Mar 2021 18:10:54

Generated On: 10 Jun 2021 10:17:24

|  |  |
|--|--|
| SAEID  | USA-US210-2021-MRNA-1273-P301000002                              |
| 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                                      | MURRAY   |
| Investigator's Last Name                                       | KIMMEL   |
| Site Address: Street   |  |
| Site Address: City   |  |
| Site Address: State  |  |
| Site Address: Postal Code                                      |  |
| Investigator Country   | US   |
| E2B Transmit Flag (Derived/Hidden)                             | 2  |

US3902021

Folder: SAE USA-US210-2021-MRNA-1273-P301000002

Form: Safety Report Form (1)

Data signed: (b) (4) 30 Mar 2021 18:10:54

Generated On: 10 Jun 2021 10:17:24

|   |  |
|---|--|
| SAEID   | USA-US210-2021-MRNA-1273-P301000002                              |
| 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   | MURRAY   |
| Investigator's Last Name  | KIMMEL   |
| Site Address: Street  |  |
| Site Address: City  |  |
| Site Address: State   |  |
| Site Address: Postal Code   |  |
| Investigator Country  | US   |
| E2B Transmit Flag (Derived/Hidden)  | 2  |
| Date of submission (Pre-filled from custom function)  | 02/MAR/2021 10:39  |
| 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   |



US3902021

Folder: SAE USA-US210-2021-MRNA-1273-P301000002

Form: Safety Report Form (2)

Data signed: (b) (4) 30 Mar 2021 18:10:54

Generated On: 10 Jun 2021 10:17:24

|   |  |
|---|--|
| SAEID   | USA-US210-2021-MRNA-1273-P301000002                              |
| 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   | MURRAY   |
| Investigator's Last Name  | KIMMEL   |
| Site Address: Street  |  |
| Site Address: City  |  |
| Site Address: State   |  |
| Site Address: Postal Code   |  |
| Investigator Country  | US   |
| E2B Transmit Flag (Derived/Hidden)  | 2  |
| Date of submission (Pre-filled from custom function)  | 18/MAR/2021 12:40  |
| Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge. | True   |

Audit

US3902021 (Prod: Synexus - Optimal Research - Melbourne)

**US3902021**

**Form: Participant Creation**

**Generated On: 10 Jun 2021 10:17:24**

[Participant ID](#)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | Murray Kimmel (b) (4)            | 30 Mar 2021 18:10:57 |
|                           |                                  |                      |
| User entered 'US3902021'  | RWS_ENDPOINT<br>ENDPOINT (b) (4) | 02 Sep 2020 20:59:25 |
|                           |                                  |                      |

**US3902021**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 10 Jun 2021 10:17:24**

[Was this visit performed?](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 28 Apr 2021 19:41:42 |
| User signature succeeded. | Murray Kimmel (b) (4)   | 30 Mar 2021 18:10:57 |
| User entered 'Yes (Y)'    | Taylor Atkinson (b) (4) | 02 Sep 2020 22:23:11 |

**US3902021**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 10 Jun 2021 10:17:24**

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

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                 | 28 Apr 2021 19:41:42 |
| User signature succeeded.  | Murray Kimmel (b) (4)            | 30 Mar 2021 18:10:57 |
| User entered '02 SEP 2020' | RWS_ENDPOINT<br>ENDPOINT (b) (4) | 02 Sep 2020 20:59:26 |

**US3902021**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 10 Jun 2021 10:17:24**

[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 19:41:42 |
| User signature succeeded.      | Murray Kimmel (b) (4)   | 30 Mar 2021 18:10:57 |
| User entered 'Clinic (Clinic)' | Taylor Atkinson (b) (4) | 02 Sep 2020 22:23:11 |

**US3902021**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 10 Jun 2021 10:17:24**

[Folder OID](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 19:41:42 |
| User entered 'SCRN' | System           | 02 Sep 2020 22:23:11 |

US3902021

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:17:24

Date of Birth (MMM yyyy)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                 | 28 Apr 2021 19:41:42 |
| User signature succeeded.  | Murray Kimmel (b) (4)            | 30 Mar 2021 18:10:57 |
| User entered (b) (6) 1982' | RWS_ENDPOINT<br>ENDPOINT (b) (4) | 02 Sep 2020 20:59:27 |



**US3902021**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 10:17:24**

[Age](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 28 Apr 2021 19:41:42 |
| User signature succeeded. | Murray Kimmel (b) (4)   | 30 Mar 2021 18:10:57 |
| User entered '38'         | Taylor Atkinson (b) (4) | 02 Sep 2020 22:50:02 |

**US3902021**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 10:17:24**

[Age Units](#)

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 28 Apr 2021 19:41:42 |
| User entered 'YEARS' | System           | 02 Sep 2020 22:50:02 |

**US3902021**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 10:17:24**

[Age \(Derived\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:41:42 |
| User entered '38' | System           | 02 Sep 2020 22:50:32 |

**US3902021**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 10:17:24**

[Sex](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 28 Apr 2021 19:41:42 |
| User signature succeeded. | Murray Kimmel (b) (4)   | 30 Mar 2021 18:10:57 |
| User entered 'Female (F)' | Taylor Atkinson (b) (4) | 02 Sep 2020 22:50:02 |

**US3902021**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 10:17:24**

[Ethnicity](#)

| Audit  | User                    | Time (GMT)           |
|--|-------------------------|----------------------|
| Data hard locked.                                      | (b) (4), (b) (6)        | 28 Apr 2021 19:41:42 |
| User signature succeeded.                              | Murray Kimmel (b) (4)   | 30 Mar 2021 18:10:57 |
| User entered 'Hispanic or Latino (HISPANIC OR LATINO)' | Taylor Atkinson (b) (4) | 02 Sep 2020 22:50:02 |

**US3902021**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 10:17:24**

[White](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 28 Apr 2021 19:41:42 |
| User signature succeeded. | Murray Kimmel (b) (4)   | 30 Mar 2021 18:10:57 |
| User entered 'I'          | Taylor Atkinson (b) (4) | 02 Sep 2020 22:50:02 |

**US3902021**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 10:17:24**

[Black](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 28 Apr 2021 19:41:42 |
| User signature succeeded. | Murray Kimmel (b) (4)   | 30 Mar 2021 18:10:57 |
| User entered '0'          | Taylor Atkinson (b) (4) | 02 Sep 2020 22:50:02 |

**US3902021**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 10:17:24**

[Asian](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 28 Apr 2021 19:41:42 |
| User signature succeeded. | Murray Kimmel (b) (4)   | 30 Mar 2021 18:10:57 |
| User entered '0'          | Taylor Atkinson (b) (4) | 02 Sep 2020 22:50:02 |



**US3902021**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 10:17:24**

[American Indian or Alaska Native](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 28 Apr 2021 19:41:42 |
| User signature succeeded. | Murray Kimmel (b) (4)   | 30 Mar 2021 18:10:57 |
| User entered '0'          | Taylor Atkinson (b) (4) | 02 Sep 2020 22:50:02 |

**US3902021**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 10:17:24**

[Native Hawaiian or other Pacific Islander](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 28 Apr 2021 19:41:42 |
| User signature succeeded. | Murray Kimmel (b) (4)   | 30 Mar 2021 18:10:57 |
| User entered '0'          | Taylor Atkinson (b) (4) | 02 Sep 2020 22:50:02 |

**US3902021**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 10:17:24**

[Other](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 28 Apr 2021 19:41:42 |
| User signature succeeded. | Murray Kimmel (b) (4)   | 30 Mar 2021 18:10:57 |
| User entered '0'          | Taylor Atkinson (b) (4) | 02 Sep 2020 22:50:02 |

**US3902021**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 10:17:24**

[If race is Other, specify](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 28 Apr 2021 19:41:42 |
| User signature succeeded. | Murray Kimmel (b) (4)   | 30 Mar 2021 18:10:57 |
| User entered empty.       | Taylor Atkinson (b) (4) | 02 Sep 2020 22:50:02 |

**US3902021**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 10:17:24**

[Unknown](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 28 Apr 2021 19:41:42 |
| User signature succeeded. | Murray Kimmel (b) (4)   | 30 Mar 2021 18:10:57 |
| User entered '0'          | Taylor Atkinson (b) (4) | 02 Sep 2020 22:50:02 |

**US3902021**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 10:17:24**

[Not reported](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 28 Apr 2021 19:41:42 |
| User signature succeeded. | Murray Kimmel (b) (4)   | 30 Mar 2021 18:10:57 |
| User entered '0'          | Taylor Atkinson (b) (4) | 02 Sep 2020 22:50:02 |

US3902021

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:17:24

Date of Informed Consent (*dd MMM yyyy*)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 28 Apr 2021 19:41:42 |
| User signature succeeded. | Murray Kimmel (b) (4)   | 30 Mar 2021 18:10:57 |
| User entered '2 Sep 2020' | Taylor Atkinson (b) (4) | 02 Sep 2020 22:50:32 |

**US3902021**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 10:17:24**

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

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| Data hard locked.       | (b) (4), (b) (6) | 28 Apr 2021 19:41:42 |
| User entered 'Sep 2020' | System           | 02 Sep 2020 22:50:32 |



**US3902021**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 10:17:24**

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 19:41:42 |
| User entered '2020' | System           | 02 Sep 2020 22:50:32 |

**US3902021**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 10:17:24**

[Protocol Version](#)

| Audit                          | User                    | Time (GMT)           |
|--------------------------------|-------------------------|----------------------|
| Data hard locked.              | (b) (4), (b) (6)        | 28 Apr 2021 19:41:42 |
| User signature succeeded.      | Murray Kimmel (b) (4)   | 30 Mar 2021 18:10:57 |
| User entered 'Amendment 3 (3)' | Taylor Atkinson (b) (4) | 02 Sep 2020 22:50:32 |

**US3902021**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 10:17:24**

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

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 28 Apr 2021 19:41:42 |
| User signature succeeded. | Murray Kimmel (b) (4)   | 30 Mar 2021 18:10:57 |
| User entered 'Yes (Y)'    | Taylor Atkinson (b) (4) | 02 Sep 2020 22:50:32 |

**US3902021**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 10:17:24**

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

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 28 Apr 2021 19:41:42 |
| User signature succeeded. | Murray Kimmel (b) (4)   | 30 Mar 2021 18:10:57 |
| User entered empty.       | Taylor Atkinson (b) (4) | 02 Sep 2020 22:50:32 |

**US3902021**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 10:17:24**

If reason for screen fail is Other, specify

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 28 Apr 2021 19:41:42 |
| User signature succeeded. | Murray Kimmel (b) (4)   | 30 Mar 2021 18:10:57 |
| User entered empty.       | Taylor Atkinson (b) (4) | 02 Sep 2020 22:50:32 |

**US3902021**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 10:17:24**

[Was this participant screened previously?](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 28 Apr 2021 19:41:42 |
| User signature succeeded. | Murray Kimmel (b) (4)   | 30 Mar 2021 18:10:57 |
| User entered 'No (N)'     | Taylor Atkinson (b) (4) | 02 Sep 2020 22:50:32 |

US3902021

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:17:24

[If Yes, previous participant number](#)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 28 Apr 2021 19:41:42 |
| User signature succeeded. | Murray Kimmel (b) (4)            | 30 Mar 2021 18:10:57 |
| User entered empty.       | RWS_ENDPOINT<br>ENDPOINT (b) (4) | 02 Sep 2020 20:59:26 |

**US3902021**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 10:17:24**

[Enrollment Trigger](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:41:42 |
| User entered 'I'  | System           | 02 Sep 2020 22:50:39 |



**US3902021**

**Folder: Screening**

**Form: Inclusion/Exclusion Criteria Summary**

**Generated On: 10 Jun 2021 10:17:24**

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

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 28 Apr 2021 19:41:42 |
| User signature succeeded. | Murray Kimmel (b) (4)   | 30 Mar 2021 18:10:57 |
| User entered 'Yes (Y)'    | Taylor Atkinson (b) (4) | 02 Sep 2020 22:50:39 |

**US3902021**

**Folder: Screening**

**Form: Medical History Summary**

**Generated On: 10 Jun 2021 10:17:24**

[Were any significant conditions reported?](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 28 Apr 2021 19:41:42 |
| User signature succeeded. | Murray Kimmel (b) (4) | 30 Mar 2021 18:10:57 |
| User entered 'No (N)'     | Bram Swarr (b) (4)    | 04 Sep 2020 14:01:13 |

**US3902021**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 10:17:24**

[Were vital signs assessed?](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 28 Apr 2021 19:41:42 |
| User signature succeeded. | Murray Kimmel (b) (4) | 30 Mar 2021 18:10:57 |
| User entered 'Yes (Y)'    | Bram Swarr (b) (4)    | 04 Sep 2020 14:01:03 |

**US3902021**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 10:17:24**

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

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 28 Apr 2021 19:41:42 |
| User signature succeeded.  | Murray Kimmel (b) (4) | 30 Mar 2021 18:10:57 |
| User entered '02 Sep 2020' | Bram Swarr (b) (4)    | 04 Sep 2020 14:01:03 |

**US3902021**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 10:17:24**

**Time of assessment (00:00-23:59)**

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 28 Apr 2021 19:41:42 |
| User signature succeeded. | Murray Kimmel (b) (4) | 30 Mar 2021 18:10:57 |
| User entered '16:48'      | Bram Swarr (b) (4)    | 04 Sep 2020 14:01:03 |

**US3902021**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 10:17:24**

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

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 28 Apr 2021 19:41:42 |
| User entered '02 Sep 2020 16:48' | System           | 04 Sep 2020 14:01:03 |

US3902021

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:17:24

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

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 28 Apr 2021 19:41:42 |
| User signature succeeded. | Murray Kimmel (b) (4) | 30 Mar 2021 18:10:57 |
| User entered '64' in      | Bram Swarr (b) (4)    | 04 Sep 2020 14:01:03 |
| DataPoint set to visible. | System                | 02 Sep 2020 22:50:39 |

US3902021

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:17:24

Weight (xxx.x)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 28 Apr 2021 19:41:42 |
| User signature succeeded. | Murray Kimmel (b) (4) | 30 Mar 2021 18:10:57 |
| User entered '134' lb     | Bram Swarr (b) (4)    | 04 Sep 2020 14:01:03 |
| DataPoint set to visible. | System                | 02 Sep 2020 22:50:39 |



**US3902021**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 10:17:24**

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

| Audit                     | User             | Time (GMT)           |
|---------------------------|------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6) | 28 Apr 2021 19:41:42 |
| User entered '23.04914'   | System           | 04 Sep 2020 14:01:03 |
| DataPoint set to visible. | System           | 02 Sep 2020 22:50:39 |

**US3902021**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 10:17:24**

[BMI units](#)

| Audit                     | User             | Time (GMT)           |
|---------------------------|------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6) | 28 Apr 2021 19:41:42 |
| User entered 'kg/m2'      | System           | 04 Sep 2020 14:01:03 |
| DataPoint set to visible. | System           | 02 Sep 2020 22:50:39 |

US3902021

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:17:24

Temperature (xxx.x)

| Audit  | User                    | Time (GMT)           |
|--|-------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)        | 28 Apr 2021 19:41:42 |
| User signature succeeded.  | Murray Kimmel (b) (4)   | 30 Mar 2021 18:10:57 |
| User closed query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening CRF. Please update accordingly. Thank you.' (Site from DM). Query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening CRF. Please update accordingly. Thank you.' answered with 'data updated' (Site from DM). | (b) (4), (b) (6)        | 28 Sep 2020 07:14:34 |
| User entered missing code ND - Not Done; reason for change Data Entry Error  | Katrina Carlson (b) (4) | 26 Sep 2020 15:40:39 |
| User opened query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening CRF. Please update accordingly. Thank you.' (Site from DM).  | (b) (4)                 | 26 Sep 2020 15:40:32 |
| User entered '97.3' F  | (b) (4), (b) (6)        | 10 Sep 2020 07:58:15 |
|  | Bram Swarr (b) (4)      | 04 Sep 2020 14:01:03 |

US3902021

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:17:24

[Route of measurement](#)

| Audit  | User                    | Time (GMT)           |
|--|-------------------------|----------------------|
| Data hard locked.                                      | (b) (4), (b) (6)        | 28 Apr 2021 19:41:42 |
| User signature succeeded.                              | Murray Kimmel (b) (4)   | 30 Mar 2021 18:10:57 |
| User entered empty; reason for change Data Entry Error | Katrina Carlson (b) (4) | 26 Sep 2020 15:40:32 |
| User entered 'Oral (Oral)'                             | Bram Swarr (b) (4)      | 04 Sep 2020 14:01:03 |

**US3902021**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 10:17:24**

[If Other, specify](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 28 Apr 2021 19:41:42 |
| User signature succeeded. | Murray Kimmel (b) (4) | 30 Mar 2021 18:10:57 |
| User entered empty.       | Bram Swarr (b) (4)    | 04 Sep 2020 14:01:03 |

US3902021

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:17:24

[Pulse \(xxx\)](#)

| Audit   | User                    | Time (GMT)           |
|---|-------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)        | 28 Apr 2021 19:41:42 |
| User signature succeeded.   | Murray Kimmel (b) (4)   | 30 Mar 2021 18:10:57 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | Katrina Carlson (b) (4) | 26 Sep 2020 15:40:32 |
| User entered '67'   | Bram Swarr (b) (4)      | 04 Sep 2020 14:01:03 |

**US3902021**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 10:17:24**

[Pulse units](#)

| Audit              | User             | Time (GMT)           |
|--------------------|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 28 Apr 2021 19:41:42 |
| User entered 'bpm' | System           | 04 Sep 2020 14:01:03 |

US3902021

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:17:24

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

| Audit   | User                    | Time (GMT)           |
|---|-------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)        | 28 Apr 2021 19:41:42 |
| User signature succeeded.   | Murray Kimmel (b) (4)   | 30 Mar 2021 18:10:57 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | Katrina Carlson (b) (4) | 26 Sep 2020 15:40:32 |
| User entered '16'   | Bram Swarr (b) (4)      | 04 Sep 2020 14:01:03 |



**US3902021**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 10:17:24**

[Respiratory Rate units](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6) | 28 Apr 2021 19:41:42 |
| User entered 'breaths/min' | System           | 04 Sep 2020 14:01:03 |

US3902021

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:17:24

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

| Audit   | User                    | Time (GMT)           |
|---|-------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)        | 28 Apr 2021 19:41:42 |
| User signature succeeded.   | Murray Kimmel (b) (4)   | 30 Mar 2021 18:10:57 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | Katrina Carlson (b) (4) | 26 Sep 2020 15:40:32 |
| User entered '103'  | Bram Swarr (b) (4)      | 04 Sep 2020 14:01:03 |

**US3902021**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 10:17:24**

[Systolic Blood Pressure units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 19:41:42 |
| User entered 'mmHg' | System           | 04 Sep 2020 14:01:03 |

US3902021

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:17:24

Diastolic Blood Pressure (xxx)

| Audit   | User                    | Time (GMT)           |
|---|-------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)        | 28 Apr 2021 19:41:42 |
| User signature succeeded.   | Murray Kimmel (b) (4)   | 30 Mar 2021 18:10:57 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | Katrina Carlson (b) (4) | 26 Sep 2020 15:40:32 |
| User entered '81'   | Bram Swarr (b) (4)      | 04 Sep 2020 14:01:03 |

**US3902021**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 10:17:24**

[Diastolic Blood Pressure units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 19:41:42 |
| User entered 'mmHg' | System           | 04 Sep 2020 14:01:03 |

**US3902021**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 10:17:24**

[Height \(derived\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:41:42 |
|                   |                  |                      |

**US3902021**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 10:17:24**

[Weight \(derived\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:41:42 |
|                   |                  |                      |

**US3902021**

**Folder: Screening**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 10:17:24**

[Was the physical examination performed?](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 28 Apr 2021 19:41:42 |
| User signature succeeded. | Murray Kimmel (b) (4) | 30 Mar 2021 18:10:57 |
| User entered 'Yes (Y)'    | Bram Swarr (b) (4)    | 04 Sep 2020 14:01:34 |



**US3902021**

**Folder: Screening**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 10:17:24**

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

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 28 Apr 2021 19:41:42 |
| User signature succeeded.  | Murray Kimmel (b) (4) | 30 Mar 2021 18:10:57 |
| User entered '02 Sep 2020' | Bram Swarr (b) (4)    | 04 Sep 2020 14:01:34 |

**US3902021**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 10 Jun 2021 10:17:24**

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

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 28 Apr 2021 19:41:42 |
| User signature succeeded.  | Murray Kimmel (b) (4) | 30 Mar 2021 18:10:57 |
| User entered '02 Sep 2020' | Bram Swarr (b) (4)    | 04 Sep 2020 14:03:04 |

US3902021

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 10:17:24

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

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 28 Apr 2021 19:41:42 |
| User signature succeeded. | Murray Kimmel (b) (4) | 30 Mar 2021 18:10:57 |
| User entered 'Yes (Y)'    | Bram Swarr (b) (4)    | 04 Sep 2020 14:03:04 |

**US3902021**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 10 Jun 2021 10:17:24**

[If No, what is the reason?](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 28 Apr 2021 19:41:42 |
| User signature succeeded. | Murray Kimmel (b) (4) | 30 Mar 2021 18:10:57 |
| User entered empty.       | Bram Swarr (b) (4)    | 04 Sep 2020 14:03:04 |

**US3902021**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 10 Jun 2021 10:17:24**

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

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 28 Apr 2021 19:41:42 |
| User signature succeeded. | Murray Kimmel (b) (4) | 30 Mar 2021 18:10:57 |
| User entered empty.       | Bram Swarr (b) (4)    | 04 Sep 2020 14:03:04 |

**US3902021**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 10 Jun 2021 10:17:24**

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

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 28 Apr 2021 19:41:42 |
| User signature succeeded. | Murray Kimmel (b) (4) | 30 Mar 2021 18:10:57 |
| User entered empty.       | Bram Swarr (b) (4)    | 04 Sep 2020 14:03:04 |

**US3902021**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 10 Jun 2021 10:17:24**

[Date of surgery unknown](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 28 Apr 2021 19:41:42 |
| User signature succeeded. | Murray Kimmel (b) (4) | 30 Mar 2021 18:10:57 |
| User entered '0'          | Bram Swarr (b) (4)    | 04 Sep 2020 14:03:04 |

US3902021

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 10:17:24

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

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 28 Apr 2021 19:41:42 |
| User signature succeeded. | Murray Kimmel (b) (4) | 30 Mar 2021 18:10:57 |
| User entered empty.       | Bram Swarr (b) (4)    | 04 Sep 2020 14:03:04 |



**US3902021**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 10 Jun 2021 10:17:24**

[Date of last menstruation unknown](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 28 Apr 2021 19:41:42 |
| User signature succeeded. | Murray Kimmel (b) (4) | 30 Mar 2021 18:10:57 |
| User entered '0'          | Bram Swarr (b) (4)    | 04 Sep 2020 14:03:04 |

**US3902021**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 10 Jun 2021 10:17:24**

[Was the pregnancy test performed?](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 28 Apr 2021 19:41:42 |
| User signature succeeded. | Murray Kimmel (b) (4) | 30 Mar 2021 18:10:57 |
| User entered 'Yes (Y)'    | Bram Swarr (b) (4)    | 04 Sep 2020 14:08:34 |

**US3902021**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 10 Jun 2021 10:17:24**

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

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 28 Apr 2021 19:41:42 |
| User signature succeeded.  | Murray Kimmel (b) (4) | 30 Mar 2021 18:10:57 |
| User entered '02 Sep 2020' | Bram Swarr (b) (4)    | 04 Sep 2020 14:08:34 |

**US3902021**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 10 Jun 2021 10:17:24**

[Test performed](#)

| Audit                        | User                  | Time (GMT)           |
|------------------------------|-----------------------|----------------------|
| Data hard locked.            | (b) (4), (b) (6)      | 28 Apr 2021 19:41:42 |
| User signature succeeded.    | Murray Kimmel (b) (4) | 30 Mar 2021 18:10:57 |
| User entered 'Urine (URINE)' | Bram Swarr (b) (4)    | 04 Sep 2020 14:08:34 |

**US3902021**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 10 Jun 2021 10:17:24**

[Result](#)

| Audit                              | User                  | Time (GMT)           |
|------------------------------------|-----------------------|----------------------|
| Data hard locked.                  | (b) (4), (b) (6)      | 28 Apr 2021 19:41:42 |
| User signature succeeded.          | Murray Kimmel (b) (4) | 30 Mar 2021 18:10:57 |
| User entered 'Negative (NEGATIVE)' | Bram Swarr (b) (4)    | 04 Sep 2020 14:08:34 |

**US3902021**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 10 Jun 2021 10:17:24**

[Was FSH sample collected?](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 28 Apr 2021 19:41:42 |
| User signature succeeded. | Murray Kimmel (b) (4) | 30 Mar 2021 18:10:57 |
| User entered 'No (N)'     | Bram Swarr (b) (4)    | 04 Sep 2020 14:08:34 |

**US3902021**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 10 Jun 2021 10:17:24**

[Collection date](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 28 Apr 2021 19:41:42 |
| User signature succeeded. | Murray Kimmel (b) (4) | 30 Mar 2021 18:10:57 |
| User entered empty.       | Bram Swarr (b) (4)    | 04 Sep 2020 14:08:34 |

**US3902021**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 10 Jun 2021 10:17:24**

[Collection time](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 28 Apr 2021 19:41:42 |
| User signature succeeded. | Murray Kimmel (b) (4) | 30 Mar 2021 18:10:57 |
| User entered empty.       | Bram Swarr (b) (4)    | 04 Sep 2020 14:08:34 |



**US3902021**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 10 Jun 2021 10:17:24**

[Collection date and time \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 19:41:42 |
| User entered empty. | System           | 04 Sep 2020 14:08:34 |

US3902021

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:17:24

**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 19:41:42 |
| User signature succeeded. | Murray Kimmel (b) (4) | 30 Mar 2021 18:10:57 |
| User entered 'No (N)'     | Bram Swarr (b) (4)    | 04 Sep 2020 14:24:27 |

US3902021

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:17:24

**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 19:41:42 |
| User signature succeeded. | Murray Kimmel (b) (4) | 30 Mar 2021 18:10:57 |
| User entered 'No (N)'     | Bram Swarr (b) (4)    | 04 Sep 2020 14:24:27 |

US3902021

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:17:24

**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 19:41:42 |
| User signature succeeded. | Murray Kimmel (b) (4) | 30 Mar 2021 18:10:57 |
| User entered 'No (N)'     | Bram Swarr (b) (4)    | 04 Sep 2020 14:24:27 |

US3902021

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:17:24

**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 19:41:42 |
| User signature succeeded. | Murray Kimmel (b) (4) | 30 Mar 2021 18:10:57 |
| User entered 'No (N)'     | Bram Swarr (b) (4)    | 04 Sep 2020 14:24:27 |

US3902021

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:17:24

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 19:41:42 |
| User signature succeeded. | Murray Kimmel (b) (4) | 30 Mar 2021 18:10:57 |
| User entered 'No (N)'     | Bram Swarr (b) (4)    | 04 Sep 2020 14:24:27 |

US3902021

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:17:24

[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 19:41:42 |
| User signature succeeded. | Murray Kimmel (b) (4) | 30 Mar 2021 18:10:57 |
| User entered 'No (N)'     | Bram Swarr (b) (4)    | 04 Sep 2020 14:24:27 |

US3902021

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:17:24

**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 19:41:42 |
| User signature succeeded. | Murray Kimmel (b) (4) | 30 Mar 2021 18:10:57 |
| User entered 'No (N)'     | Bram Swarr (b) (4)    | 04 Sep 2020 14:24:27 |



US3902021

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:17:24

**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 19:41:42 |
| User signature succeeded. | Murray Kimmel (b) (4) | 30 Mar 2021 18:10:57 |
| User entered 'No (N)'     | Bram Swarr (b) (4)    | 04 Sep 2020 14:24:27 |

US3902021

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:17:24

[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 19:41:42 |
| User signature succeeded. | Murray Kimmel (b) (4) | 30 Mar 2021 18:10:57 |
| User entered 'No (N)'     | Bram Swarr (b) (4)    | 04 Sep 2020 14:24:27 |

US3902021

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:17:24

**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 19:41:42 |
| User signature succeeded. | Murray Kimmel (b) (4) | 30 Mar 2021 18:10:57 |
| User entered 'No (N)'     | Bram Swarr (b) (4)    | 04 Sep 2020 14:24:27 |

US3902021

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:17:24

**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 19:41:42 |
| User signature succeeded. | Murray Kimmel (b) (4) | 30 Mar 2021 18:10:57 |
| User entered 'No (N)'     | Bram Swarr (b) (4)    | 04 Sep 2020 14:24:27 |

**US3902021**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 10 Jun 2021 10:17:24**

**Other**

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 28 Apr 2021 19:41:42 |
| User signature succeeded. | Murray Kimmel (b) (4) | 30 Mar 2021 18:10:57 |
| User entered 'No (N)'     | Bram Swarr (b) (4)    | 04 Sep 2020 14:24:27 |

US3902021

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:17:24

[Specify](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 28 Apr 2021 19:41:42 |
| User signature succeeded. | Murray Kimmel (b) (4) | 30 Mar 2021 18:10:57 |
| User entered empty.       | Bram Swarr (b) (4)    | 04 Sep 2020 14:24:27 |

US3902021

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:17:24

No Risk Identified

| Audit   | User                  | Time (GMT)           |
|---|-----------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)      | 28 Apr 2021 19:41:42 |
| User signature succeeded.   | Murray Kimmel (b) (4) | 30 Mar 2021 18:10:57 |
| User closed query "No Risk Identified" is not checked, however no other risks are selected. Please review and reconcile.' (Site from System). | System                | 26 Sep 2020 15:43:56 |
| User opened query "No Risk Identified" is not checked, however no other risks are selected. Please review and reconcile.' (Site from System). | System                | 04 Sep 2020 14:24:27 |
| User entered '0'  | Bram Swarr (b) (4)    | 04 Sep 2020 14:24:27 |

US3902021

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:17:24

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

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 28 Apr 2021 19:41:42 |
| User signature succeeded. | Murray Kimmel (b) (4) | 30 Mar 2021 18:10:57 |
| User entered '0'          | Bram Swarr (b) (4)    | 04 Sep 2020 14:24:27 |



US3902021

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:17:24

**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 19:41:42 |
| User signature succeeded. | Murray Kimmel (b) (4) | 30 Mar 2021 18:10:57 |
| User entered '0'          | Bram Swarr (b) (4)    | 04 Sep 2020 14:24:27 |

US3902021

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:17:24

[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 19:41:42 |
| User signature succeeded. | Murray Kimmel (b) (4) | 30 Mar 2021 18:10:57 |
| User entered '0'          | Bram Swarr (b) (4)    | 04 Sep 2020 14:24:27 |

US3902021

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:17:24

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 19:41:42 |
| User signature succeeded. | Murray Kimmel (b) (4) | 30 Mar 2021 18:10:57 |
| User entered '0'          | Bram Swarr (b) (4)    | 04 Sep 2020 14:24:27 |

US3902021

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:17:24

[Resides in a single family home](#) (i.e., detached housing)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 28 Apr 2021 19:41:42 |
| User signature succeeded. | Murray Kimmel (b) (4) | 30 Mar 2021 18:10:57 |
| User entered '0'          | Bram Swarr (b) (4)    | 04 Sep 2020 14:24:27 |

US3902021

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:17:24

[Other](#)

| Audit  | User                    | Time (GMT)           |
|--|-------------------------|----------------------|
| Data hard locked.                                    | (b) (4), (b) (6)        | 28 Apr 2021 19:41:42 |
| User signature succeeded.                            | Murray Kimmel (b) (4)   | 30 Mar 2021 18:10:57 |
| User entered '1' reason for change: Data Entry Error | Katrina Carlson (b) (4) | 26 Sep 2020 15:43:56 |
| User entered '0'                                     | Bram Swarr (b) (4)      | 04 Sep 2020 14:24:27 |

US3902021

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:17:24

[Specify](#)

| Audit   | User                    | Time (GMT)           |
|---|-------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)        | 28 Apr 2021 19:41:42 |
| User signature succeeded.   | Murray Kimmel (b) (4)   | 30 Mar 2021 18:10:57 |
| User entered 'condominium with one other person'<br>reason for change: Data Entry Error | Katrina Carlson (b) (4) | 26 Sep 2020 15:43:56 |
| User entered empty.   | Bram Swarr (b) (4)      | 04 Sep 2020 14:24:27 |

**US3902021**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 10 Jun 2021 10:17:24**

[Was this visit performed?](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 14 Apr 2021 06:18:15 |
| User signature succeeded. | Murray Kimmel (b) (4) | 30 Mar 2021 18:10:57 |
| User entered 'Yes (Y)'    | Bram Swarr (b) (4)    | 04 Sep 2020 14:24:57 |

**US3902021**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 10 Jun 2021 10:17:24**

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

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 14 Apr 2021 06:18:15 |
| User signature succeeded.  | Murray Kimmel (b) (4) | 30 Mar 2021 18:10:57 |
| User entered '02 Sep 2020' | Bram Swarr (b) (4)    | 04 Sep 2020 14:24:57 |



**US3902021**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 10 Jun 2021 10:17:24**

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

| Audit                          | User                  | Time (GMT)           |
|--------------------------------|-----------------------|----------------------|
| Data hard locked.              | (b) (4), (b) (6)      | 14 Apr 2021 06:18:15 |
| User signature succeeded.      | Murray Kimmel (b) (4) | 30 Mar 2021 18:10:57 |
| User entered 'Clinic (Clinic)' | Bram Swarr (b) (4)    | 04 Sep 2020 14:24:57 |

**US3902021**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 10 Jun 2021 10:17:24**

[Folder OID](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| Data hard locked.     | (b) (4), (b) (6) | 14 Apr 2021 06:18:15 |
| User entered 'VISIT1' | System           | 04 Sep 2020 14:24:57 |

US3902021

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:17:24

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

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                 | 14 Apr 2021 06:18:15 |
| User signature succeeded.  | Murray Kimmel (b) (4)            | 30 Mar 2021 18:10:57 |
| User entered '02 SEP 2020' | RWS_ENDPOINT<br>ENDPOINT (b) (4) | 02 Sep 2020 22:14:22 |

**US3902021**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 10 Jun 2021 10:17:24**

[What was the participant's randomization number?](#)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 14 Apr 2021 06:18:15 |
| User signature succeeded. | Murray Kimmel (b) (4)            | 30 Mar 2021 18:10:57 |
| User entered '111222'     | RWS_ENDPOINT<br>ENDPOINT (b) (4) | 02 Sep 2020 22:14:22 |

US3902021

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:17:24

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

| Audit   | User                             | Time (GMT)           |
|---|----------------------------------|----------------------|
| Data hard locked.                                     | (b) (4), (b) (6)                 | 14 Apr 2021 06:18:15 |
| User signature succeeded.                             | Murray Kimmel (b) (4)            | 30 Mar 2021 18:10:57 |
| User entered '>=18 and <65 years and not at risk (1)' | RWS_ENDPOINT<br>ENDPOINT (b) (4) | 02 Sep 2020 22:14:22 |

US3902021

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:17:24

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)        | 14 Apr 2021 06:18:15 |
| User signature succeeded.   | Murray Kimmel (b) (4)   | 30 Mar 2021 18:10:57 |
| User closed query 'Per CDM: Please complete this section of the form (a required response (Yes or No) is needed for each), otherwise explain.' (Site from DM).                  | (b) (4), (b) (6)        | 28 Sep 2020 07:14:05 |
| Query 'Per CDM: Please complete this section of the form (a required response (Yes or No) is needed for each), otherwise explain.' answered with 'data updated' (Site from DM). | Katrina Carlson (b) (4) | 26 Sep 2020 15:40:08 |
| User entered 'No (N)'   | Bram Swarr (b) (4)      | 04 Sep 2020 14:31:31 |
| User opened query 'Per CDM: Please complete this section of the form (a required response (Yes or No) is needed for each), otherwise explain.' (Site from DM).                  | (b) (4), (b) (6)        | 03 Sep 2020 14:57:44 |

**US3902021**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 10 Jun 2021 10:17:24**

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)      | 14 Apr 2021 06:18:15 |
| User signature succeeded. | Murray Kimmel (b) (4) | 30 Mar 2021 18:10:57 |
| User entered 'No (N)'     | Bram Swarr (b) (4)    | 04 Sep 2020 14:31:31 |

**US3902021**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 10 Jun 2021 10:17:24**

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

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 14 Apr 2021 06:18:15 |
| User signature succeeded. | Murray Kimmel (b) (4) | 30 Mar 2021 18:10:57 |
| User entered 'No (N)'     | Bram Swarr (b) (4)    | 04 Sep 2020 14:31:31 |



**US3902021**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 10 Jun 2021 10:17:24**

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

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 14 Apr 2021 06:18:15 |
| User signature succeeded. | Murray Kimmel (b) (4) | 30 Mar 2021 18:10:57 |
| User entered 'No (N)'     | Bram Swarr (b) (4)    | 04 Sep 2020 14:31:31 |

**US3902021**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 10 Jun 2021 10:17:24**

[Liver Disease](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 14 Apr 2021 06:18:15 |
| User signature succeeded. | Murray Kimmel (b) (4) | 30 Mar 2021 18:10:57 |
| User entered 'No (N)'     | Bram Swarr (b) (4)    | 04 Sep 2020 14:31:31 |

**US3902021**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 10 Jun 2021 10:17:24**

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

| Audit  | User                    | Time (GMT)           |
|--|-------------------------|----------------------|
| Data hard locked.                            | (b) (4), (b) (6)        | 14 Apr 2021 06:18:15 |
| User signature succeeded.                    | Murray Kimmel (b) (4)   | 30 Mar 2021 18:10:57 |
| User entered 'No (N)'                        | Katrina Carlson (b) (4) | 26 Sep 2020 15:40:03 |
| Amendment Manager: DataPoint set to visible. | System                  | 19 Sep 2020 05:02:29 |
| Amendment Manager inserted this DataPoint.   | System                  | 19 Sep 2020 05:02:27 |

US3902021

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:17:24

[Height](#)

| Audit  | User                    | Time (GMT)           |
|--|-------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)        | 14 Apr 2021 06:18:15 |
| User signature succeeded.  | Murray Kimmel (b) (4)   | 30 Mar 2021 18:10:57 |
| User closed query 'Per CDM: As per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT. Please update accordingly. Thank you.' (Site from DM).                 | (b) (4), (b) (6)        | 28 Sep 2020 07:13:00 |
| Query 'Per CDM: As per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT. Please update accordingly. Thank you.' answered with 'data updaed' (Site from DM). | Katrina Carlson (b) (4) | 26 Sep 2020 15:39:53 |
| User entered missing code ND - Not Done; reason for change Data Entry Error  | (b) (4)                 | 26 Sep 2020 15:39:48 |
| User opened query 'Per CDM: As per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT. Please update accordingly. Thank you.' (Site from DM).                 | (b) (4), (b) (6)        | 17 Sep 2020 09:50:46 |
| User entered '64' in   | Bram Swarr (b) (4)      | 04 Sep 2020 14:34:01 |

US3902021

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:17:24

[Weight](#)

| Audit   | User                    | Time (GMT)           |
|---|-------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)        | 14 Apr 2021 06:18:15 |
| User signature succeeded.   | Murray Kimmel (b) (4)   | 30 Mar 2021 18:10:57 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | Katrina Carlson (b) (4) | 26 Sep 2020 15:39:48 |
| User entered '134' lb   | Bram Swarr (b) (4)      | 04 Sep 2020 14:34:01 |

US3902021

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:17:24

Height

| Audit  | User                    | Time (GMT)           |
|--|-------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)        | 14 Apr 2021 06:18:15 |
| User signature succeeded.  | Murray Kimmel (b) (4)   | 30 Mar 2021 18:10:57 |
| User closed query 'Per CDM: As per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT. Please update accordingly. Thank you.' (Site from DM).                 | (b) (4), (b) (6)        | 28 Sep 2020 07:13:00 |
| Query 'Per CDM: As per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT. Please update accordingly. Thank you.' answered with 'data updaed' (Site from DM). | Katrina Carlson (b) (4) | 26 Sep 2020 15:39:53 |
| User entered missing code ND - Not Done; reason for change Data Entry Error  | (b) (4)                 | 26 Sep 2020 15:39:48 |
| User opened query 'Per CDM: As per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT. Please update accordingly. Thank you.' (Site from DM).                 | (b) (4), (b) (6)        | 17 Sep 2020 09:50:46 |
| User entered '64' in   | Bram Swarr (b) (4)      | 04 Sep 2020 14:34:01 |

US3902021

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:17:24

[Weight](#)

| Audit   | User                    | Time (GMT)           |
|---|-------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)        | 14 Apr 2021 06:18:15 |
| User signature succeeded.   | Murray Kimmel (b) (4)   | 30 Mar 2021 18:10:57 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | Katrina Carlson (b) (4) | 26 Sep 2020 15:39:48 |
| User entered '134' lb   | Bram Swarr (b) (4)      | 04 Sep 2020 14:34:01 |

US3902021

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:17:24

[Timepoint](#)

| Audit  | User               | Time (GMT)           |
|--|--------------------|----------------------|
| Data hard locked.                                | (b) (4), (b) (6)   | 14 Apr 2021 06:18:15 |
| User accepted default value 'Pre-Dose (PREDOSE)' | Bram Swarr (b) (4) | 04 Sep 2020 14:34:01 |



US3902021

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:17:24

[Were vital signs assessed?](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 14 Apr 2021 06:18:15 |
| User signature succeeded. | Murray Kimmel (b) (4) | 30 Mar 2021 18:10:57 |
| User entered 'Yes (Y)'    | Bram Swarr (b) (4)    | 04 Sep 2020 14:34:01 |

**US3902021**

**Folder: Visit 1 Day 1**

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

**Generated On: 10 Jun 2021 10:17:24**

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

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 14 Apr 2021 06:18:15 |
| User signature succeeded.  | Murray Kimmel (b) (4) | 30 Mar 2021 18:10:57 |
| User entered '02 Sep 2020' | Bram Swarr (b) (4)    | 04 Sep 2020 14:34:01 |

**US3902021**

**Folder: Visit 1 Day 1**

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

**Generated On: 10 Jun 2021 10:17:24**

**Time of assessment (00:00-23:59)**

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 14 Apr 2021 06:18:15 |
| User signature succeeded. | Murray Kimmel (b) (4) | 30 Mar 2021 18:10:57 |
| User entered '16:48'      | Bram Swarr (b) (4)    | 04 Sep 2020 14:34:01 |

**US3902021**

**Folder: Visit 1 Day 1**

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

**Generated On: 10 Jun 2021 10:17:24**

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

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 14 Apr 2021 06:18:15 |
| User entered '02 Sep 2020 16:48' | System           | 04 Sep 2020 14:34:01 |

US3902021

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:17:24

Temperature (xxx.x)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 14 Apr 2021 06:18:15 |
| User signature succeeded. | Murray Kimmel (b) (4) | 30 Mar 2021 18:10:57 |
| User entered '97.3' F     | Bram Swarr (b) (4)    | 04 Sep 2020 14:34:01 |

**US3902021**

**Folder: Visit 1 Day 1**

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

**Generated On: 10 Jun 2021 10:17:24**

[Route of measurement](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 14 Apr 2021 06:18:15 |
| User signature succeeded.  | Murray Kimmel (b) (4) | 30 Mar 2021 18:10:57 |
| User entered 'Oral (Oral)' | Bram Swarr (b) (4)    | 04 Sep 2020 14:34:01 |

US3902021

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:17:24

[If Other, specify](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 14 Apr 2021 06:18:15 |
| User signature succeeded. | Murray Kimmel (b) (4) | 30 Mar 2021 18:10:57 |
| User entered empty.       | Bram Swarr (b) (4)    | 04 Sep 2020 14:34:01 |

**US3902021**

**Folder: Visit 1 Day 1**

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

**Generated On: 10 Jun 2021 10:17:24**

[Pulse \(xxx\)](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 14 Apr 2021 06:18:15 |
| User signature succeeded. | Murray Kimmel (b) (4) | 30 Mar 2021 18:10:57 |
| User entered '67'         | Bram Swarr (b) (4)    | 04 Sep 2020 14:34:01 |



**US3902021**

**Folder: Visit 1 Day 1**

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

**Generated On: 10 Jun 2021 10:17:24**

[Pulse units](#)

| Audit              | User             | Time (GMT)           |
|--------------------|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 14 Apr 2021 06:18:15 |
| User entered 'bpm' | System           | 04 Sep 2020 14:34:01 |

**US3902021**

**Folder: Visit 1 Day 1**

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

**Generated On: 10 Jun 2021 10:17:24**

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

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 14 Apr 2021 06:18:15 |
| User signature succeeded. | Murray Kimmel (b) (4) | 30 Mar 2021 18:10:57 |
| User entered '16'         | Bram Swarr (b) (4)    | 04 Sep 2020 14:34:01 |

**US3902021**

**Folder: Visit 1 Day 1**

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

**Generated On: 10 Jun 2021 10:17:24**

[Respiratory Rate units](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6) | 14 Apr 2021 06:18:15 |
| User entered 'breaths/min' | System           | 04 Sep 2020 14:34:01 |

US3902021

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:17:24

Systolic Blood Pressure (xxx)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 14 Apr 2021 06:18:15 |
| User signature succeeded. | Murray Kimmel (b) (4) | 30 Mar 2021 18:10:57 |
| User entered '103'        | Bram Swarr (b) (4)    | 04 Sep 2020 14:34:01 |

**US3902021**

**Folder: Visit 1 Day 1**

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

**Generated On: 10 Jun 2021 10:17:24**

[Systolic Blood Pressure units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 14 Apr 2021 06:18:15 |
| User entered 'mmHg' | System           | 04 Sep 2020 14:34:01 |

US3902021

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:17:24

Diastolic Blood Pressure (xxx)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 14 Apr 2021 06:18:15 |
| User signature succeeded. | Murray Kimmel (b) (4) | 30 Mar 2021 18:10:57 |
| User entered '81'         | Bram Swarr (b) (4)    | 04 Sep 2020 14:34:01 |

**US3902021**

**Folder: Visit 1 Day 1**

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

**Generated On: 10 Jun 2021 10:17:24**

[Diastolic Blood Pressure units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 14 Apr 2021 06:18:15 |
| User entered 'mmHg' | System           | 04 Sep 2020 14:34:01 |

US3902021

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:17:24

Height

| Audit  | User                    | Time (GMT)           |
|--|-------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)        | 14 Apr 2021 06:18:15 |
| User signature succeeded.  | Murray Kimmel (b) (4)   | 30 Mar 2021 18:10:57 |
| User closed query 'Per CDM: As per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT. Please update accordingly. Thank you.' (Site from DM).                 | (b) (4), (b) (6)        | 28 Sep 2020 07:13:00 |
| Query 'Per CDM: As per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT. Please update accordingly. Thank you.' answered with 'data updaed' (Site from DM). | Katrina Carlson (b) (4) | 26 Sep 2020 15:39:53 |
| User entered missing code ND - Not Done; reason for change Data Entry Error  | (b) (4)                 | 26 Sep 2020 15:39:48 |
| User opened query 'Per CDM: As per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT. Please update accordingly. Thank you.' (Site from DM).                 | (b) (4), (b) (6)        | 17 Sep 2020 09:50:46 |
| User entered '64' in   | Bram Swarr (b) (4)      | 04 Sep 2020 14:34:01 |



US3902021

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:17:24

[Weight](#)

| Audit   | User                    | Time (GMT)           |
|---|-------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)        | 14 Apr 2021 06:18:15 |
| User signature succeeded.   | Murray Kimmel (b) (4)   | 30 Mar 2021 18:10:57 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | Katrina Carlson (b) (4) | 26 Sep 2020 15:39:48 |
| User entered '134' lb   | Bram Swarr (b) (4)      | 04 Sep 2020 14:34:01 |

US3902021

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:17:24

[Timepoint](#)

| Audit  | User               | Time (GMT)           |
|--|--------------------|----------------------|
| Data hard locked.                                  | (b) (4), (b) (6)   | 14 Apr 2021 06:18:15 |
| User accepted default value 'Post-Dose (POSTDOSE)' | Bram Swarr (b) (4) | 04 Sep 2020 14:34:01 |

US3902021

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:17:24

Were vital signs assessed?

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 14 Apr 2021 06:18:15 |
| User signature succeeded. | Murray Kimmel (b) (4) | 30 Mar 2021 18:10:57 |
| User entered 'Yes (Y)'    | Bram Swarr (b) (4)    | 04 Sep 2020 14:34:01 |

**US3902021**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 10:17:24**

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

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 14 Apr 2021 06:18:15 |
| User signature succeeded.  | Murray Kimmel (b) (4) | 30 Mar 2021 18:10:57 |
| User entered '02 Sep 2020' | Bram Swarr (b) (4)    | 04 Sep 2020 14:34:01 |

**US3902021**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 10:17:24**

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

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 14 Apr 2021 06:18:15 |
| User signature succeeded. | Murray Kimmel (b) (4) | 30 Mar 2021 18:10:57 |
| User entered '19:15'      | Bram Swarr (b) (4)    | 04 Sep 2020 14:34:01 |

**US3902021**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 10:17:24**

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

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 14 Apr 2021 06:18:15 |
| User entered '02 Sep 2020 19:15' | System           | 04 Sep 2020 14:34:01 |

US3902021

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:17:24

Temperature (xxx.x)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 14 Apr 2021 06:18:15 |
| User signature succeeded. | Murray Kimmel (b) (4) | 30 Mar 2021 18:10:57 |
| User entered '97.3' F     | Bram Swarr (b) (4)    | 04 Sep 2020 14:34:01 |

**US3902021**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 10:17:24**

[Route of measurement](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 14 Apr 2021 06:18:15 |
| User signature succeeded.  | Murray Kimmel (b) (4) | 30 Mar 2021 18:10:57 |
| User entered 'Oral (Oral)' | Bram Swarr (b) (4)    | 04 Sep 2020 14:34:01 |



US3902021

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:17:24

[If Other, specify](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 14 Apr 2021 06:18:15 |
| User signature succeeded. | Murray Kimmel (b) (4) | 30 Mar 2021 18:10:57 |
| User entered empty.       | Bram Swarr (b) (4)    | 04 Sep 2020 14:34:01 |

**US3902021**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 10:17:24**

[Pulse \(xxx\)](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 14 Apr 2021 06:18:15 |
| User signature succeeded. | Murray Kimmel (b) (4) | 30 Mar 2021 18:10:57 |
| User entered '68'         | Bram Swarr (b) (4)    | 04 Sep 2020 14:34:01 |

**US3902021**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 10:17:24**

[Pulse units](#)

| Audit              | User             | Time (GMT)           |
|--------------------|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 14 Apr 2021 06:18:15 |
| User entered 'bpm' | System           | 04 Sep 2020 14:34:01 |

US3902021

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:17:24

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

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 14 Apr 2021 06:18:15 |
| User signature succeeded. | Murray Kimmel (b) (4) | 30 Mar 2021 18:10:57 |
| User entered '16'         | Bram Swarr (b) (4)    | 04 Sep 2020 14:34:01 |

**US3902021**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 10:17:24**

[Respiratory Rate units](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6) | 14 Apr 2021 06:18:15 |
| User entered 'breaths/min' | System           | 04 Sep 2020 14:34:01 |

US3902021

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:17:24

Systolic Blood Pressure (xxx)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 14 Apr 2021 06:18:15 |
| User signature succeeded. | Murray Kimmel (b) (4) | 30 Mar 2021 18:10:57 |
| User entered '98'         | Bram Swarr (b) (4)    | 04 Sep 2020 14:34:01 |

**US3902021**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 10:17:24**

[Systolic Blood Pressure units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 14 Apr 2021 06:18:15 |
| User entered 'mmHg' | System           | 04 Sep 2020 14:34:01 |

US3902021

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:17:24

Diastolic Blood Pressure (xxx)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 14 Apr 2021 06:18:15 |
| User signature succeeded. | Murray Kimmel (b) (4) | 30 Mar 2021 18:10:57 |
| User entered '66'         | Bram Swarr (b) (4)    | 04 Sep 2020 14:34:01 |



US3902021

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:17:24

Diastolic Blood Pressure units

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 14 Apr 2021 06:18:15 |
| User entered 'mmHg' | System           | 04 Sep 2020 14:34:01 |

US3902021

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 10:17:24

Was the physical examination performed?

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 14 Apr 2021 06:18:15 |
| User signature succeeded. | Murray Kimmel (b) (4) | 30 Mar 2021 18:10:57 |
| User entered 'Yes (Y)'    | Bram Swarr (b) (4)    | 04 Sep 2020 14:30:06 |

**US3902021**

**Folder: Visit 1 Day 1**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 10:17:24**

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

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 14 Apr 2021 06:18:15 |
| User signature succeeded.  | Murray Kimmel (b) (4) | 30 Mar 2021 18:10:57 |
| User entered '02 Sep 2020' | Bram Swarr (b) (4)    | 04 Sep 2020 14:30:06 |

US3902021

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 10:17:24

Was the pregnancy test performed?

| Audit  | User                    | Time (GMT)           |
|--|-------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)        | 14 Apr 2021 06:18:15 |
| User signature succeeded.  | Murray Kimmel (b) (4)   | 30 Mar 2021 18:10:57 |
| User closed query 'Per CDM: Per CCG's pages 15-16, please record this as NO and remove date for pregnancy test and PE forms at Visit 1 Day 1. Thank you.' (Site from DM).                  | (b) (4), (b) (6)        | 28 Sep 2020 07:13:24 |
| Query 'Per CDM: Per CCG's pages 15-16, please record this as NO and remove date for pregnancy test and PE forms at Visit 1 Day 1. Thank you.' answered with 'data updated' (Site from DM). | Katrina Carlson (b) (4) | 26 Sep 2020 15:42:10 |
| User entered 'No (N)' reason for change: Data Entry Error  | (b) (4)                 | 26 Sep 2020 15:41:21 |
| User opened query 'Per CDM: Per CCG's pages 15-16, please record this as NO and remove date for pregnancy test and PE forms at Visit 1 Day 1. Thank you.' (Site from DM).                  | (b) (4), (b) (6)        | 08 Sep 2020 04:59:53 |
| User entered 'Yes (Y)'   | Bram Swarr (b) (4)      | 04 Sep 2020 14:26:25 |

US3902021

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 10:17:24

Date of test (dd MMM yyyy)

| Audit  | User                    | Time (GMT)           |
|--|-------------------------|----------------------|
| Data hard locked.                                      | (b) (4), (b) (6)        | 14 Apr 2021 06:18:15 |
| User signature succeeded.                              | Murray Kimmel (b) (4)   | 30 Mar 2021 18:10:57 |
| User entered empty; reason for change Data Entry Error | Katrina Carlson (b) (4) | 26 Sep 2020 15:41:21 |
| User entered '02 Sep 2020'                             | Bram Swarr (b) (4)      | 04 Sep 2020 14:26:25 |

**US3902021**

**Folder: Visit 1 Day 1**

**Form: Pregnancy Test**

**Generated On: 10 Jun 2021 10:17:24**

[Test performed](#)

| Audit  | User                    | Time (GMT)           |
|--|-------------------------|----------------------|
| Data hard locked.                                      | (b) (4), (b) (6)        | 14 Apr 2021 06:18:15 |
| User signature succeeded.                              | Murray Kimmel (b) (4)   | 30 Mar 2021 18:10:57 |
| User entered empty; reason for change Data Entry Error | Katrina Carlson (b) (4) | 26 Sep 2020 15:41:21 |
| User entered 'Urine (URINE)'                           | Bram Swarr (b) (4)      | 04 Sep 2020 14:26:25 |

US3902021

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 10:17:24

[Result](#)

| Audit  | User                    | Time (GMT)           |
|--|-------------------------|----------------------|
| Data hard locked.                                      | (b) (4), (b) (6)        | 14 Apr 2021 06:18:15 |
| User signature succeeded.                              | Murray Kimmel (b) (4)   | 30 Mar 2021 18:10:57 |
| User entered empty; reason for change Data Entry Error | Katrina Carlson (b) (4) | 26 Sep 2020 15:41:21 |
| User entered 'Negative (NEGATIVE)'                     | Bram Swarr (b) (4)      | 04 Sep 2020 14:26:25 |

US3902021

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 10:17:24

[Was FSH sample collected?](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 14 Apr 2021 06:18:15 |
| User signature succeeded. | Murray Kimmel (b) (4) | 30 Mar 2021 18:10:57 |
| User entered 'No (N)'     | Bram Swarr (b) (4)    | 04 Sep 2020 14:26:25 |



**US3902021**

**Folder: Visit 1 Day 1**

**Form: Pregnancy Test**

**Generated On: 10 Jun 2021 10:17:24**

[Collection date](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 14 Apr 2021 06:18:15 |
| User signature succeeded. | Murray Kimmel (b) (4) | 30 Mar 2021 18:10:57 |
| User entered empty.       | Bram Swarr (b) (4)    | 04 Sep 2020 14:26:25 |

**US3902021**

**Folder: Visit 1 Day 1**

**Form: Pregnancy Test**

**Generated On: 10 Jun 2021 10:17:24**

[Collection time](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 14 Apr 2021 06:18:15 |
| User signature succeeded. | Murray Kimmel (b) (4) | 30 Mar 2021 18:10:57 |
| User entered empty.       | Bram Swarr (b) (4)    | 04 Sep 2020 14:26:25 |

**US3902021**

**Folder: Visit 1 Day 1**

**Form: Pregnancy Test**

**Generated On: 10 Jun 2021 10:17:24**

[Collection date and time \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 14 Apr 2021 06:18:15 |
| User entered empty. | System           | 04 Sep 2020 14:26:25 |

US3902021

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:17:24

[Was study treatment given?](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 14 Apr 2021 06:18:15 |
| User signature succeeded. | Murray Kimmel (b) (4)   | 30 Mar 2021 18:10:57 |
| User entered 'Yes (Y)'    | Taylor Atkinson (b) (4) | 02 Sep 2020 22:51:19 |

US3902021

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:17:24

If No, reason not given

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 14 Apr 2021 06:18:15 |
| User signature succeeded. | Murray Kimmel (b) (4)   | 30 Mar 2021 18:10:57 |
| User entered empty.       | Taylor Atkinson (b) (4) | 02 Sep 2020 22:51:19 |

US3902021

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:17:24

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)        | 14 Apr 2021 06:18:15 |
| User signature succeeded. | Murray Kimmel (b) (4)   | 30 Mar 2021 18:10:57 |
| User entered empty.       | Taylor Atkinson (b) (4) | 02 Sep 2020 22:51:19 |

**US3902021**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 10 Jun 2021 10:17:24**

[What was the study treatment?](#)

| Audit                               | User             | Time (GMT)           |
|-------------------------------------|------------------|----------------------|
| Data hard locked.                   | (b) (4), (b) (6) | 14 Apr 2021 06:18:15 |
| User entered 'MRNA-1273 OR PLACEBO' | System           | 02 Sep 2020 22:51:19 |

US3902021

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:17:24

What was the treatment date? (dd MMM yyyy)

| Audit   | User                    | Time (GMT)           |
|---|-------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)        | 14 Apr 2021 06:18:15 |
| User signature succeeded.   | Murray Kimmel (b) (4)   | 30 Mar 2021 18:10:57 |
| User closed query 'Per CDM: Date format is not correctly recorded in Treatment 1 date. Please review the Date field, it must be 2 digits (dd-MMM-yyyy) format (e.g. 02-SEP-2020). Leading zeroes are acceptable, if applicable. Please update accordingly.' (Site from DM).               | (b) (4), (b) (6)        | 27 Oct 2020 08:13:17 |
| Query 'Per CDM: Date format is not correctly recorded in Treatment 1 date. Please review the Date field, it must be 2 digits (dd-MMM-yyyy) format (e.g. 02-SEP-2020). Leading zeroes are acceptable, if applicable. Please update accordingly.' answered with 'Corrected' (Site from DM). | Taylor Atkinson (b) (4) | 22 Oct 2020 22:42:15 |
| User entered '02 Sep 2020' reason for change: Data Entry Error  | (b) (4)                 | 22 Oct 2020 22:42:03 |
| User opened query 'Per CDM: Date format is not correctly recorded in Treatment 1 date. Please review the Date field, it must be 2 digits (dd-MMM-yyyy) format (e.g. 02-SEP-2020). Leading zeroes are acceptable, if applicable. Please update accordingly.' (Site from DM).               | (b) (4), (b) (6)        | 22 Oct 2020 13:06:50 |
| User entered '2 Sep 2020'   | Taylor Atkinson (b) (4) | 02 Sep 2020 22:51:19 |



**US3902021**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 10 Jun 2021 10:17:24**

[What was the treatment time? \(00:00-23:59\)](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 14 Apr 2021 06:18:15 |
| User signature succeeded. | Murray Kimmel (b) (4)   | 30 Mar 2021 18:10:57 |
| User entered '18:40'      | Taylor Atkinson (b) (4) | 02 Sep 2020 22:51:19 |

**US3902021**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 10 Jun 2021 10:17:24**

[Treatment Date and Time \(derived\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 14 Apr 2021 06:18:15 |
| User entered '02 Sep 2020 18:40' | System           | 22 Oct 2020 22:42:03 |
| User entered '2 Sep 2020 18:40'  | System           | 02 Sep 2020 22:51:19 |

**US3902021**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 10 Jun 2021 10:17:24**

[Which arm was used to give treatment?](#)

| Audit                              | User                    | Time (GMT)           |
|------------------------------------|-------------------------|----------------------|
| Data hard locked.                  | (b) (4), (b) (6)        | 14 Apr 2021 06:18:15 |
| User signature succeeded.          | Murray Kimmel (b) (4)   | 30 Mar 2021 18:10:57 |
| User entered 'Left Arm (LEFT ARM)' | Taylor Atkinson (b) (4) | 02 Sep 2020 22:51:19 |

US3902021

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:17:24

[What was the frequency of the study treatment dosing?](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 14 Apr 2021 06:18:15 |
| User entered 'ONCE' | System           | 02 Sep 2020 22:51:19 |

US3902021

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:17:24

What was the route of administration for the study treatment?

| Audit                        | User             | Time (GMT)           |
|------------------------------|------------------|----------------------|
| Data hard locked.            | (b) (4), (b) (6) | 14 Apr 2021 06:18:15 |
| User entered 'INTRAMUSCULAR' | System           | 02 Sep 2020 22:51:19 |

US3902021

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:17:24

[Was the sample collected?](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 14 Apr 2021 06:18:15 |
| User signature succeeded. | Murray Kimmel (b) (4) | 30 Mar 2021 18:10:57 |
| User entered 'Yes (Y)'    | Bram Swarr (b) (4)    | 04 Sep 2020 14:26:55 |

**US3902021**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 10:17:24**

**Collection date** (*dd MMM yyyy*)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 14 Apr 2021 06:18:15 |
| User signature succeeded. | Murray Kimmel (b) (4) | 30 Mar 2021 18:10:57 |
| User entered '2 Sep 2020' | Bram Swarr (b) (4)    | 04 Sep 2020 14:26:55 |

**US3902021**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 10:17:24**

[Collection time \(00:00-23:59\)](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 14 Apr 2021 06:18:15 |
| User signature succeeded. | Murray Kimmel (b) (4) | 30 Mar 2021 18:10:57 |
| User entered '18:03'      | Bram Swarr (b) (4)    | 04 Sep 2020 14:26:55 |



**US3902021**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 10:17:24**

[Collection date and time \(derived\)](#)

| Audit                           | User             | Time (GMT)           |
|---------------------------------|------------------|----------------------|
| Data hard locked.               | (b) (4), (b) (6) | 14 Apr 2021 06:18:15 |
| User entered '2 Sep 2020 18:03' | System           | 04 Sep 2020 14:26:55 |

US3902021

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 10:17:24

Collection date (*dd MMM yyyy*)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 14 Apr 2021 06:18:15 |
| User signature succeeded.  | Murray Kimmel (b) (4) | 30 Mar 2021 18:10:57 |
| User entered '02 Sep 2020' | Bram Swarr (b) (4)    | 04 Sep 2020 14:29:21 |

**US3902021**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 10:17:24**

[Lab Test](#)

| Audit  | User               | Time (GMT)           |
|--|--------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)   | 14 Apr 2021 06:18:15 |
| User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)' | Bram Swarr (b) (4) | 04 Sep 2020 14:29:21 |

US3902021

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:17:24

[Was the sample collected?](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 14 Apr 2021 06:18:15 |
| User signature succeeded. | Murray Kimmel (b) (4) | 30 Mar 2021 18:10:57 |
| User entered 'Yes (Y)'    | Bram Swarr (b) (4)    | 04 Sep 2020 14:29:21 |

**US3902021**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 10:17:24**

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

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 14 Apr 2021 06:18:15 |
| User signature succeeded. | Murray Kimmel (b) (4) | 30 Mar 2021 18:10:57 |
| User entered '18:04'      | Bram Swarr (b) (4)    | 04 Sep 2020 14:29:21 |

**US3902021**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 10:17:24**

[Collection date and time \(derived\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 14 Apr 2021 06:18:15 |
| User entered '02 Sep 2020 18:04' | System           | 04 Sep 2020 14:29:21 |

**US3902021**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 10:17:24**

[Lab Test](#)

| Audit  | User               | Time (GMT)           |
|--|--------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)   | 14 Apr 2021 06:18:15 |
| User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)' | Bram Swarr (b) (4) | 04 Sep 2020 14:29:21 |

US3902021

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:17:24

[Was the sample collected?](#)

| Audit  | User                    | Time (GMT)           |
|--|-------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)        | 14 Apr 2021 06:18:15 |
| User signature succeeded.  | Murray Kimmel (b) (4)   | 30 Mar 2021 18:10:57 |
| User closed query 'Data is required. Please complete.' (Site from System).             | System                  | 09 Sep 2020 10:53:32 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System                  | 09 Sep 2020 10:53:32 |
| User entered 'No (N)' reason for change: Data Entry Error                              | Taylor Atkinson (b) (4) | 09 Sep 2020 10:53:32 |
| User opened query 'Data is required. Please complete.' (Site from System).             | System                  | 04 Sep 2020 14:29:21 |
| User entered empty.  | Bram Swarr (b) (4)      | 04 Sep 2020 14:29:21 |



**US3902021**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 10:17:24**

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

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 14 Apr 2021 06:18:15 |
| User signature succeeded. | Murray Kimmel (b) (4) | 30 Mar 2021 18:10:57 |
| User entered empty.       | Bram Swarr (b) (4)    | 04 Sep 2020 14:29:21 |

**US3902021**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 10:17:24**

[Collection date and time \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 14 Apr 2021 06:18:15 |
| User entered empty. | System           | 04 Sep 2020 14:29:21 |

**US3902021**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 10 Jun 2021 10:17:24**

[Is the participant continuing to the next visit?](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 14 Apr 2021 06:18:15 |
| User signature succeeded. | Murray Kimmel (b) (4) | 30 Mar 2021 18:10:57 |
| User entered 'Yes (Y)'    | Bram Swarr (b) (4)    | 04 Sep 2020 14:34:28 |

**US3902021**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 10 Jun 2021 10:17:24**

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 06:18:15 |
| User entered 'I'  | System           | 04 Sep 2020 14:34:28 |

US3902021

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 10:17:24

**TIMEPOINT**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| Data entry locked.   | System           | 02 Sep 2020 22:51:19 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System           | 02 Sep 2020 22:51:19 |

US3902021

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 10:17:24

Was **TEMPERATURE** taken?

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-09-02T19:11:38', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '0add0e09-219d-4931-9558-b49c633e97f7' User entered 'Yes (Y)' | System           | 02 Sep 2020 23:12:23 |
|   | System           | 02 Sep 2020 23:12:23 |

US3902021

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 10:17:24

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-09-02T19:11:55', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '0add0e09-219d-4931-9558-b49c633e97f7' User entered '97.3' | System           | 02 Sep 2020 23:12:23 |
|  | System           | 02 Sep 2020 23:12:23 |

US3902021

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 10:17:24

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-09-02T19:12:08', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '0add0e09-219d-4931-9558-b49c633e97f7' | System           | 02 Sep 2020 23:12:23 |
| User entered 'No (N)'  | System           | 02 Sep 2020 23:12:23 |



**US3902021**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 10:17:24**

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-09-02T19:12:19', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '0add0e09-219d-4931-9558-b49c633e97f7' User entered '02 Sep 2020 19:12' | System           | 02 Sep 2020 23:12:23 |
|   | System           | 02 Sep 2020 23:12:23 |

US3902021

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 10:17:24

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| User entered '02 Sep 2020 19:00' | System           | 02 Sep 2020 22:51:19 |

**US3902021**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 10:17:24**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| User entered '02 Sep 2020 21:30' | System           | 02 Sep 2020 22:51:19 |

US3902021

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 10:17:24

**TIMEPOINT**

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                                 | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| Data entry locked.                                | System           | 02 Sep 2020 22:51:19 |
| User entered 'Day 1, after vaccination (at home)' | System           | 02 Sep 2020 22:51:19 |

US3902021

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 10:17:24

Was **TEMPERATURE** taken?

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-09-03T08:48:31', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: 'a93e6814-0fd6-484e-b1cf-e4455e64f15c' User entered 'Yes (Y)' | System           | 03 Sep 2020 12:48:47 |
|   | System           | 03 Sep 2020 12:48:47 |

US3902021

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 10:17:24

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-09-03T08:48:35', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: 'a93e6814-0fd6-484e-b1cf-e4455e64f15c' User entered '98.2' | System           | 03 Sep 2020 12:48:47 |
|  | System           | 03 Sep 2020 12:48:47 |

US3902021

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 10:17:24

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-09-03T08:48:39', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: 'a93e6814-0fd6-484e-b1cf-e4455e64f15c' User entered 'No (N)' | System           | 03 Sep 2020 12:48:47 |
|  | System           | 03 Sep 2020 12:48:47 |

**US3902021**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 10:17:24**

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-09-03T08:48:44', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: 'a93e6814-0fd6-484e-b1cf-e4455e64f15c' User entered '03 Sep 2020 08:48' | System           | 03 Sep 2020 12:48:47 |
|   | System           | 03 Sep 2020 12:48:47 |



**US3902021**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 10:17:24**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| User entered '02 Sep 2020 22:25' | System           | 02 Sep 2020 22:51:19 |

**US3902021**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 10:17:24**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| User entered '03 Sep 2020 11:59' | System           | 02 Sep 2020 22:51:19 |

**US3902021**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 10 Jun 2021 10:17:24**

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| Data entry locked.   | System           | 02 Sep 2020 22:51:19 |
| User entered 'Day 2' | System           | 02 Sep 2020 22:51:19 |

**US3902021**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 10 Jun 2021 10:17:24**

**Was TEMPERATURE taken?**

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-09-04T09:44:04', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '37a80e93-f284-4ccb-843b-7d0fab1470eb' User entered 'Yes (Y)' | System           | 04 Sep 2020 13:45:14 |
|   | System           | 04 Sep 2020 13:45:14 |

US3902021

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 10:17:24

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-09-04T09:44:44', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '37a80e93-f284-4ccb-843b-7d0fab1470eb' User entered '98.2' | System           | 04 Sep 2020 13:45:14 |
|  | System           | 04 Sep 2020 13:45:14 |

US3902021

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 10:17:24

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-09-04T09:44:48', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '37a80e93-f284-4ccb-843b-7d0fab1470eb' User entered 'No (N)' | System           | 04 Sep 2020 13:45:14 |
|  | System           | 04 Sep 2020 13:45:14 |

**US3902021**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 10 Jun 2021 10:17:24**

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-09-04T09:45:11', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '37a80e93-f284-4ccb-843b-7d0fab1470eb' User entered '04 Sep 2020 09:45' | System           | 04 Sep 2020 13:45:14 |
|   | System           | 04 Sep 2020 13:45:14 |

**US3902021**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 10 Jun 2021 10:17:24**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| User entered '03 Sep 2020 12:00' | System           | 02 Sep 2020 22:51:19 |



**US3902021**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 10 Jun 2021 10:17:24**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| User entered '04 Sep 2020 11:59' | System           | 02 Sep 2020 22:51:19 |

**US3902021**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 10:17:24**

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| Data entry locked.   | System           | 02 Sep 2020 22:51:19 |
| User entered 'Day 3' | System           | 02 Sep 2020 22:51:19 |

US3902021

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 10:17:24

Was **TEMPERATURE** taken?

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-09-05T09:21:44', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '18990c4f-c832-41d0-b059-b38c85c5ee62' User entered 'Yes (Y)' | System           | 05 Sep 2020 13:22:33 |
|   | System           | 05 Sep 2020 13:22:33 |

US3902021

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 10:17:24

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-09-05T09:22:22', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '18990c4f-c832-41d0-b059-b38c85c5ee62' User entered '97.7' | System           | 05 Sep 2020 13:22:33 |
|  | System           | 05 Sep 2020 13:22:33 |

US3902021

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 10:17:24

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-09-05T09:22:24', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '18990c4f-c832-41d0-b059-b38c85c5ee62' | System           | 05 Sep 2020 13:22:33 |
| User entered 'No (N)'  | System           | 05 Sep 2020 13:22:33 |

**US3902021**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 10:17:24**

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-09-05T09:22:29', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '18990c4f-c832-41d0-b059-b38c85c5ee62' | System           | 05 Sep 2020 13:22:33 |
| User entered '05 Sep 2020 09:22'   | System           | 05 Sep 2020 13:22:33 |

**US3902021**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 10:17:24**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| User entered '04 Sep 2020 12:00' | System           | 02 Sep 2020 22:51:19 |

**US3902021**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 10:17:24**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| User entered '05 Sep 2020 11:59' | System           | 02 Sep 2020 22:51:19 |



**US3902021**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 10 Jun 2021 10:17:24**

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| Data entry locked.   | System           | 02 Sep 2020 22:51:19 |
| User entered 'Day 4' | System           | 02 Sep 2020 22:51:19 |

**US3902021**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 10 Jun 2021 10:17:24**

**Was TEMPERATURE taken?**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-09-06T09:40:32', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '0e7c4fa8-1a70-4c65-96ec-ff23cab25442' | System           | 06 Sep 2020 13:40:53 |
| User entered 'Yes (Y)'   | System           | 06 Sep 2020 13:40:53 |

US3902021

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 10:17:24

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-09-06T09:40:39', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '0e7c4fa8-1a70-4c65-96ec-ff23cab25442' User entered '98.1' | System           | 06 Sep 2020 13:40:53 |
|  | System           | 06 Sep 2020 13:40:53 |

US3902021

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 10:17:24

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-09-06T09:40:42', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '0e7c4fa8-1a70-4c65-96ec-ff23cab25442' | System           | 06 Sep 2020 13:40:53 |
| User entered 'No (N)'  | System           | 06 Sep 2020 13:40:53 |

**US3902021**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 10 Jun 2021 10:17:24**

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-09-06T09:40:50', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '0e7c4fa8-1a70-4c65-96ec-ff23cab25442' | System           | 06 Sep 2020 13:40:53 |
| User entered '06 Sep 2020 09:40'   | System           | 06 Sep 2020 13:40:53 |

**US3902021**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 10 Jun 2021 10:17:24**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| User entered '05 Sep 2020 12:00' | System           | 02 Sep 2020 22:51:19 |

**US3902021**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 10 Jun 2021 10:17:24**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| User entered '06 Sep 2020 11:59' | System           | 02 Sep 2020 22:51:19 |

US3902021

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 10:17:24

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| Data entry locked.   | System           | 02 Sep 2020 22:51:19 |
| User entered 'Day 5' | System           | 02 Sep 2020 22:51:19 |



US3902021

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 10:17:24

Was **TEMPERATURE** taken?

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
|                   |                  |                      |

US3902021

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 10:17:24

Please record your **TEMPERATURE** in °F

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
|                   |                  |                      |

US3902021

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 10:17:24

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

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
|                   |                  |                      |

US3902021

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 10:17:24

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

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
|                   |                  |                      |

US3902021

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 10:17:24

To **PREVENT** pain or fever from occurring

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
|                   |                  |                      |

**US3902021**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 10:17:24**

[PC Time Stamp](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
|                   |                  |                      |

**US3902021**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 10:17:24**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| User entered '06 Sep 2020 12:00' | System           | 02 Sep 2020 22:51:19 |

**US3902021**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 10:17:24**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| User entered '07 Sep 2020 11:59' | System           | 02 Sep 2020 22:51:19 |



**US3902021**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 10:17:24**

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| Data entry locked.   | System           | 02 Sep 2020 22:51:19 |
| User entered 'Day 6' | System           | 02 Sep 2020 22:51:19 |

US3902021

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 10:17:24

Was **TEMPERATURE** taken?

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-09-07T12:42:33', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '3e64f959-3ae4-473c-930b-dda335e220df' User entered 'Yes (Y)' | System           | 07 Sep 2020 16:42:50 |
|   | System           | 07 Sep 2020 16:42:50 |

US3902021

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 10:17:24

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-09-07T12:42:42', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '3e64f959-3ae4-473c-930b-dda335e220df' User entered '98.6' | System           | 07 Sep 2020 16:42:50 |
|  | System           | 07 Sep 2020 16:42:50 |

US3902021

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 10:17:24

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-09-07T12:42:44', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '3e64f959-3ae4-473c-930b-dda335e220df' User entered 'No (N)' | System           | 07 Sep 2020 16:42:50 |
|  | System           | 07 Sep 2020 16:42:50 |

**US3902021**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 10:17:24**

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-09-07T12:42:49', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '3e64f959-3ae4-473c-930b-dda335e220df' User entered '07 Sep 2020 12:42' | System           | 07 Sep 2020 16:42:50 |
|   | System           | 07 Sep 2020 16:42:50 |

**US3902021**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 10:17:24**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| User entered '07 Sep 2020 12:00' | System           | 02 Sep 2020 22:51:19 |

**US3902021**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 10:17:24**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| User entered '08 Sep 2020 11:59' | System           | 02 Sep 2020 22:51:19 |

US3902021

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 10:17:24

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| Data entry locked.   | System           | 02 Sep 2020 22:51:19 |
| User entered 'Day 7' | System           | 02 Sep 2020 22:51:19 |



**US3902021**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 10:17:24**

**Was TEMPERATURE taken?**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-09-09T09:35:59', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '0c8fbf3a-123f-453f-a524-f5c38bcbbf13' | System           | 09 Sep 2020 13:36:10 |
| User entered 'Yes (Y)'   | System           | 09 Sep 2020 13:36:10 |

US3902021

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 10:17:24

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-09-09T09:36:01', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '0c8fbf3a-123f-453f-a524-f5c38bcbbf13' User entered '98.1' | System           | 09 Sep 2020 13:36:10 |
|  | System           | 09 Sep 2020 13:36:10 |

US3902021

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 10:17:24

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-09-09T09:36:07', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '0c8fbf3a-123f-453f-a524-f5c38bcbbf13' | System           | 09 Sep 2020 13:36:10 |
| User entered 'No (N)'  | System           | 09 Sep 2020 13:36:10 |

**US3902021**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 10:17:24**

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-09-09T09:36:09', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '0c8fbf3a-123f-453f-a524-f5c38bcbbf13' | System           | 09 Sep 2020 13:36:10 |
| User entered '09 Sep 2020 09:36'   | System           | 09 Sep 2020 13:36:10 |

**US3902021**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 10:17:24**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| User entered '08 Sep 2020 12:00' | System           | 02 Sep 2020 22:51:19 |

**US3902021**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 10:17:24**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| User entered '09 Sep 2020 11:59' | System           | 02 Sep 2020 22:51:19 |

US3902021

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 10:17:24

**TIMEPOINT**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| Data entry locked.   | System           | 02 Sep 2020 22:51:19 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System           | 02 Sep 2020 22:51:19 |

US3902021

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 10:17:24

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-09-02T19:12:28', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '8c5d7f72-4438-486b-90a4-57af4a91f14a' | System           | 02 Sep 2020 23:12:48 |
| User entered 'None (1)'  | System           | 02 Sep 2020 23:12:48 |



US3902021

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 10:17:24

Is there any REDNESS AT INJECTION SITE?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-09-02T19:12:31', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '8c5d7f72-4438-486b-90a4-57af4a91f14a' User entered 'No (N)' | System           | 02 Sep 2020 23:12:48 |
|  | System           | 02 Sep 2020 23:12:48 |

US3902021

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 10:17:24

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-09-02T19:12:34', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '8c5d7f72-4438-486b-90a4-57af4a91f14a' | System           | 02 Sep 2020 23:12:48 |
| User entered 'No (N)'  | System           | 02 Sep 2020 23:12:48 |

US3902021

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 10:17:24

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-09-02T19:12:38', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '8c5d7f72-4438-486b-90a4-57af4a91f14a' | System           | 02 Sep 2020 23:12:48 |
| User entered 'None (1)'  | System           | 02 Sep 2020 23:12:48 |

**US3902021**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 10:17:24**

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-09-02T19:12:46', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '8c5d7f72-4438-486b-90a4-57af4a91f14a' | System           | 02 Sep 2020 23:12:48 |
| User entered '02 Sep 2020 19:12'   | System           | 02 Sep 2020 23:12:48 |

**US3902021**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 10:17:24**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| User entered '02 Sep 2020 19:00' | System           | 02 Sep 2020 22:51:19 |

**US3902021**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 10:17:24**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| User entered '02 Sep 2020 21:30' | System           | 02 Sep 2020 22:51:19 |

US3902021

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 10:17:24

**TIMEPOINT**

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                                 | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| Data entry locked.                                | System           | 02 Sep 2020 22:51:19 |
| User entered 'Day 1, after vaccination (at home)' | System           | 02 Sep 2020 22:51:19 |

US3902021

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 10:17:24

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-09-03T08:35:33', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: 'aed75f00-27a3-466a-8fad-0cb78c6e2e31' | System           | 03 Sep 2020 12:37:46 |
| User entered 'Does not interfere with activity (2)'  | System           | 03 Sep 2020 12:37:46 |



US3902021

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 10:17:24

Is there any REDNESS AT INJECTION SITE?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-09-03T08:35:42', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: 'aed75f00-27a3-466a-8fad-0cb78c6e2e31' User entered 'No (N)' | System           | 03 Sep 2020 12:37:46 |
|  | System           | 03 Sep 2020 12:37:46 |

US3902021

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 10:17:24

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-09-03T08:37:26', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: 'aed75f00-27a3-466a-8fad-0cb78c6e2e31' User entered 'No (N)' | System           | 03 Sep 2020 12:37:46 |
|  | System           | 03 Sep 2020 12:37:46 |

US3902021

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 10:17:24

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-09-03T08:37:35', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: 'aed75f00-27a3-466a-8fad-0cb78c6e2e31' User entered 'None (1)' | System           | 03 Sep 2020 12:37:46 |
|  | System           | 03 Sep 2020 12:37:46 |

**US3902021**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 10:17:24**

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-09-03T08:37:45', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: 'aed75f00-27a3-466a-8fad-0cb78c6e2e31' User entered '03 Sep 2020 08:37' | System           | 03 Sep 2020 12:37:46 |
|   | System           | 03 Sep 2020 12:37:46 |

**US3902021**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 10:17:24**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| User entered '02 Sep 2020 22:25' | System           | 02 Sep 2020 22:51:19 |

**US3902021**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 10:17:24**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| User entered '03 Sep 2020 11:59' | System           | 02 Sep 2020 22:51:19 |

**US3902021**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 10:17:24**

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| Data entry locked.   | System           | 02 Sep 2020 22:51:19 |
| User entered 'Day 2' | System           | 02 Sep 2020 22:51:19 |

US3902021

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 10:17:24

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-09-04T09:45:18', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '3931fa9b-c53f-4018-b621-48216943fd12' | System           | 04 Sep 2020 13:45:46 |
| User entered 'Does not interfere with activity (2)'  | System           | 04 Sep 2020 13:45:46 |



US3902021

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 10:17:24

Is there any REDNESS AT INJECTION SITE?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-09-04T09:45:26', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '3931fa9b-c53f-4018-b621-48216943fd12' User entered 'No (N)' | System           | 04 Sep 2020 13:45:46 |
|  | System           | 04 Sep 2020 13:45:46 |

US3902021

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 10:17:24

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-09-04T09:45:30', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '3931fa9b-c53f-4018-b621-48216943fd12' User entered 'No (N)' | System           | 04 Sep 2020 13:45:46 |
|  | System           | 04 Sep 2020 13:45:46 |

US3902021

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 10:17:24

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-09-04T09:45:37', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '3931fa9b-c53f-4018-b621-48216943fd12' User entered 'None (1)' | System           | 04 Sep 2020 13:45:46 |
|  | System           | 04 Sep 2020 13:45:46 |

**US3902021**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 10:17:24**

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-09-04T09:45:42', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '3931fa9b-c53f-4018-b621-48216943fd12' User entered '04 Sep 2020 09:45' | System           | 04 Sep 2020 13:45:46 |
|   | System           | 04 Sep 2020 13:45:46 |

**US3902021**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 10:17:24**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| User entered '03 Sep 2020 12:00' | System           | 02 Sep 2020 22:51:19 |

**US3902021**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 10:17:24**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| User entered '04 Sep 2020 11:59' | System           | 02 Sep 2020 22:51:19 |

**US3902021**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 10:17:24**

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| Data entry locked.   | System           | 02 Sep 2020 22:51:19 |
| User entered 'Day 3' | System           | 02 Sep 2020 22:51:19 |

US3902021

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 10:17:24

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-09-05T09:22:36', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: 'e1d8486f-2cfa-4d89-8e89-67793c3c80f0' | System           | 05 Sep 2020 13:22:53 |
| User entered 'None (1)'  | System           | 05 Sep 2020 13:22:53 |



US3902021

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 10:17:24

Is there any REDNESS AT INJECTION SITE?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-09-05T09:22:40', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: 'e1d8486f-2cfa-4d89-8e89-67793c3c80f0' | System           | 05 Sep 2020 13:22:53 |
| User entered 'No (N)'  | System           | 05 Sep 2020 13:22:53 |

US3902021

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 10:17:24

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-09-05T09:22:42', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: 'e1d8486f-2cfa-4d89-8e89-67793c3c80f0' | System           | 05 Sep 2020 13:22:53 |
| User entered 'No (N)'  | System           | 05 Sep 2020 13:22:53 |

US3902021

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 10:17:24

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-09-05T09:22:45', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: 'e1d8486f-2cfa-4d89-8e89-67793c3c80f0' | System           | 05 Sep 2020 13:22:53 |
| User entered 'None (1)'  | System           | 05 Sep 2020 13:22:53 |

**US3902021**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 10:17:24**

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-09-05T09:22:49', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: 'e1d8486f-2cfa-4d89-8e89-67793c3c80f0' User entered '05 Sep 2020 09:22' | System           | 05 Sep 2020 13:22:53 |
|   | System           | 05 Sep 2020 13:22:53 |

**US3902021**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 10:17:24**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| User entered '04 Sep 2020 12:00' | System           | 02 Sep 2020 22:51:19 |

**US3902021**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 10:17:24**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| User entered '05 Sep 2020 11:59' | System           | 02 Sep 2020 22:51:19 |

**US3902021**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 10:17:24**

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| Data entry locked.   | System           | 02 Sep 2020 22:51:19 |
| User entered 'Day 4' | System           | 02 Sep 2020 22:51:19 |

US3902021

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 10:17:24

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-09-06T09:40:54', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: 'cccd854f-6ea6-4ae5-924c-9e4534f3e99d' | System           | 06 Sep 2020 13:41:32 |
| User entered 'None (1)'  | System           | 06 Sep 2020 13:41:32 |



US3902021

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 10:17:24

Is there any REDNESS AT INJECTION SITE?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-09-06T09:41:01', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: 'cccd854f-6ea6-4ae5-924c-9e4534f3e99d' | System           | 06 Sep 2020 13:41:32 |
| User entered 'No (N)'  | System           | 06 Sep 2020 13:41:32 |

US3902021

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 10:17:24

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-09-06T09:41:09', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: 'cccd854f-6ea6-4ae5-924c-9e4534f3e99d' | System           | 06 Sep 2020 13:41:32 |
| User entered 'No (N)'  | System           | 06 Sep 2020 13:41:32 |

US3902021

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 10:17:24

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-09-06T09:41:22', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: 'cccd854f-6ea6-4ae5-924c-9e4534f3e99d' | System           | 06 Sep 2020 13:41:32 |
| User entered 'None (1)'  | System           | 06 Sep 2020 13:41:32 |

**US3902021**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 10:17:24**

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-09-06T09:41:28', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: 'cccd854f-6ea6-4ae5-924c-9e4534f3e99d' User entered '06 Sep 2020 09:41' | System           | 06 Sep 2020 13:41:32 |
|   | System           | 06 Sep 2020 13:41:32 |

**US3902021**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 10:17:24**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| User entered '05 Sep 2020 12:00' | System           | 02 Sep 2020 22:51:19 |

**US3902021**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 10:17:24**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| User entered '06 Sep 2020 11:59' | System           | 02 Sep 2020 22:51:19 |

**US3902021**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 10:17:24**

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| Data entry locked.   | System           | 02 Sep 2020 22:51:19 |
| User entered 'Day 5' | System           | 02 Sep 2020 22:51:19 |

US3902021

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 10:17:24

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

Please select one response below

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
|                   |                  |                      |



US3902021

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 10:17:24

Is there any REDNESS AT INJECTION SITE?

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
|                   |                  |                      |

US3902021

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 10:17:24

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

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

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
|                   |                  |                      |

US3902021

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 10:17:24

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

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
|                   |                  |                      |

US3902021

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 10:17:24

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

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

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
|                   |                  |                      |

US3902021

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 10:17:24

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

Please select one response below

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
|                   |                  |                      |

**US3902021**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 10:17:24**

[PC Time Stamp](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
|                   |                  |                      |

**US3902021**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 10:17:24**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| User entered '06 Sep 2020 12:00' | System           | 02 Sep 2020 22:51:19 |

**US3902021**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 10:17:24**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| User entered '07 Sep 2020 11:59' | System           | 02 Sep 2020 22:51:19 |



**US3902021**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 10:17:24**

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| Data entry locked.   | System           | 02 Sep 2020 22:51:19 |
| User entered 'Day 6' | System           | 02 Sep 2020 22:51:19 |

US3902021

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 10:17:24

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-09-07T12:41:14', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: 'a6087a67-800a-46ac-8de3-c561f7a09642' | System           | 07 Sep 2020 16:41:30 |
| User entered 'None (1)'  | System           | 07 Sep 2020 16:41:30 |

US3902021

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 10:17:24

Is there any REDNESS AT INJECTION SITE?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-09-07T12:41:16', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: 'a6087a67-800a-46ac-8de3-c561f7a09642' | System           | 07 Sep 2020 16:41:30 |
| User entered 'No (N)'  | System           | 07 Sep 2020 16:41:30 |

US3902021

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 10:17:24

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-09-07T12:41:18', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: 'a6087a67-800a-46ac-8de3-c561f7a09642' User entered 'No (N)' | System           | 07 Sep 2020 16:41:30 |
|  | System           | 07 Sep 2020 16:41:30 |

US3902021

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 10:17:24

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-09-07T12:41:20', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: 'a6087a67-800a-46ac-8de3-c561f7a09642' | System           | 07 Sep 2020 16:41:30 |
| User entered 'None (1)'  | System           | 07 Sep 2020 16:41:30 |

**US3902021**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 10:17:24**

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-09-07T12:41:28', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: 'a6087a67-800a-46ac-8de3-c561f7a09642' User entered '07 Sep 2020 12:41' | System           | 07 Sep 2020 16:41:30 |
|   | System           | 07 Sep 2020 16:41:30 |

**US3902021**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 10:17:24**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| User entered '07 Sep 2020 12:00' | System           | 02 Sep 2020 22:51:19 |

**US3902021**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 10:17:24**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| User entered '08 Sep 2020 11:59' | System           | 02 Sep 2020 22:51:19 |



**US3902021**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 10:17:24**

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| Data entry locked.   | System           | 02 Sep 2020 22:51:19 |
| User entered 'Day 7' | System           | 02 Sep 2020 22:51:19 |

US3902021

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 10:17:24

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-09-09T09:36:17', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: 'e8ba6d25-9e44-4ef2-bae6-63c172c80899' | System           | 09 Sep 2020 13:36:37 |
| User entered 'None (1)'  | System           | 09 Sep 2020 13:36:37 |

US3902021

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 10:17:24

Is there any REDNESS AT INJECTION SITE?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-09-09T09:36:24', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: 'e8ba6d25-9e44-4ef2-bae6-63c172c80899' User entered 'No (N)' | System           | 09 Sep 2020 13:36:37 |
|  | System           | 09 Sep 2020 13:36:37 |

US3902021

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 10:17:24

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-09-09T09:36:26', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: 'e8ba6d25-9e44-4ef2-bae6-63c172c80899' User entered 'No (N)' | System           | 09 Sep 2020 13:36:37 |
|  | System           | 09 Sep 2020 13:36:37 |

US3902021

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 10:17:24

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-09-09T09:36:31', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: 'e8ba6d25-9e44-4ef2-bae6-63c172c80899' | System           | 09 Sep 2020 13:36:37 |
| User entered 'None (1)'  | System           | 09 Sep 2020 13:36:37 |

**US3902021**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 10:17:24**

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-09-09T09:36:34', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: 'e8ba6d25-9e44-4ef2-bae6-63c172c80899' | System           | 09 Sep 2020 13:36:37 |
| User entered '09 Sep 2020 09:36'   | System           | 09 Sep 2020 13:36:37 |

**US3902021**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 10:17:24**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| User entered '08 Sep 2020 12:00' | System           | 02 Sep 2020 22:51:19 |

**US3902021**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 10:17:24**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| User entered '09 Sep 2020 11:59' | System           | 02 Sep 2020 22:51:19 |



US3902021

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 10:17:24

**TIMEPOINT**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| Data entry locked.   | System           | 02 Sep 2020 22:51:19 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System           | 02 Sep 2020 22:51:19 |

**US3902021**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 10:17:24**

**HEADACHE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-09-02T19:12:51', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '05ef50fa-1365-4d33-8d24-1566694959d3' User entered 'None (0)' | System           | 02 Sep 2020 23:13:32 |
|  | System           | 02 Sep 2020 23:13:32 |

**US3902021**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 10:17:24**

**FATIGUE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-09-02T19:12:54', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '05ef50fa-1365-4d33-8d24-1566694959d3' User entered 'None (0)' | System           | 02 Sep 2020 23:13:32 |
|  | System           | 02 Sep 2020 23:13:32 |

**US3902021**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 10:17:24**

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-09-02T19:12:57', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '05ef50fa-1365-4d33-8d24-1566694959d3' User entered 'None (0)' | System           | 02 Sep 2020 23:13:32 |
|  | System           | 02 Sep 2020 23:13:32 |

US3902021

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 10:17:24

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-09-02T19:13:00', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '05ef50fa-1365-4d33-8d24-1566694959d3' User entered 'None (0)' | System           | 02 Sep 2020 23:13:32 |
|  | System           | 02 Sep 2020 23:13:32 |

**US3902021**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 10:17:24**

**NAUSEA/VOMITING**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-09-02T19:13:03', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '05ef50fa-1365-4d33-8d24-1566694959d3' User entered 'None (0)' | System           | 02 Sep 2020 23:13:32 |
|  | System           | 02 Sep 2020 23:13:32 |

**US3902021**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 10:17:24**

**CHILLS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-09-02T19:13:07', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '05ef50fa-1365-4d33-8d24-1566694959d3' User entered 'None (0)' | System           | 02 Sep 2020 23:13:32 |
|  | System           | 02 Sep 2020 23:13:32 |

US3902021

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 10:17:24

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) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-09-02T19:13:21', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '05ef50fa-1365-4d33-8d24-1566694959d3' User entered 'No (N)' | System           | 02 Sep 2020 23:13:32 |
|  | System           | 02 Sep 2020 23:13:32 |



**US3902021**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 10:17:24**

[PC Time stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-09-02T19:13:30', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '05ef50fa-1365-4d33-8d24-1566694959d3' User entered '02 Sep 2020 19:13' | System           | 02 Sep 2020 23:13:32 |
|   | System           | 02 Sep 2020 23:13:32 |

**US3902021**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 10:17:24**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| User entered '02 Sep 2020 19:00' | System           | 02 Sep 2020 22:51:19 |

**US3902021**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 10:17:24**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| User entered '02 Sep 2020 21:30' | System           | 02 Sep 2020 22:51:19 |

**US3902021**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 10:17:24**

**TIMEPOINT**

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                                 | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| Data entry locked.                                | System           | 02 Sep 2020 22:51:19 |
| User entered 'Day 1, after vaccination (at home)' | System           | 02 Sep 2020 22:51:19 |

**US3902021**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 10:17:24**

**HEADACHE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-09-03T08:37:54', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '08652849-b5bf-4dff-bd20-83dfad0340bb' User entered 'None (0)' | System           | 03 Sep 2020 12:38:22 |
|  | System           | 03 Sep 2020 12:38:22 |

**US3902021**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 10:17:24**

**FATIGUE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-09-03T08:37:57', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '08652849-b5bf-4dff-bd20-83dfad0340bb' User entered 'None (0)' | System           | 03 Sep 2020 12:38:22 |
|  | System           | 03 Sep 2020 12:38:22 |

**US3902021**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 10:17:24**

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-09-03T08:38:02', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '08652849-b5bf-4dff-bd20-83dfad0340bb' User entered 'None (0)' | System           | 03 Sep 2020 12:38:22 |
|  | System           | 03 Sep 2020 12:38:22 |

**US3902021**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 10:17:24**

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-09-03T08:38:06', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '08652849-b5bf-4dff-bd20-83dfad0340bb' User entered 'None (0)' | System           | 03 Sep 2020 12:38:22 |
|  | System           | 03 Sep 2020 12:38:22 |



**US3902021**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 10:17:24**

**NAUSEA/VOMITING**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-09-03T08:38:08', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '08652849-b5bf-4dff-bd20-83dfad0340bb' User entered 'None (0)' | System           | 03 Sep 2020 12:38:22 |
|  | System           | 03 Sep 2020 12:38:22 |

**US3902021**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 10:17:24**

**CHILLS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-09-03T08:38:10', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '08652849-b5bf-4dff-bd20-83dfad0340bb' User entered 'None (0)' | System           | 03 Sep 2020 12:38:22 |
|  | System           | 03 Sep 2020 12:38:22 |

US3902021

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 10:17:24

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) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-09-03T08:38:15', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '08652849-b5bf-4dff-bd20-83dfad0340bb' User entered 'No (N)' | System           | 03 Sep 2020 12:38:22 |
|  | System           | 03 Sep 2020 12:38:22 |

**US3902021**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 10:17:24**

[PC Time stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-09-03T08:38:18', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '08652849-b5bf-4dff-bd20-83dfad0340bb' User entered '03 Sep 2020 08:38' | System           | 03 Sep 2020 12:38:22 |
|   | System           | 03 Sep 2020 12:38:22 |

**US3902021**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 10:17:24**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| User entered '02 Sep 2020 22:25' | System           | 02 Sep 2020 22:51:19 |

**US3902021**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 10:17:24**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| User entered '03 Sep 2020 11:59' | System           | 02 Sep 2020 22:51:19 |

US3902021

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 10:17:24

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| Data entry locked.   | System           | 02 Sep 2020 22:51:19 |
| User entered 'Day 2' | System           | 02 Sep 2020 22:51:19 |

**US3902021**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 10:17:24**

**HEADACHE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-09-04T09:45:46', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: 'ee0d9fb8-1773-47c7-bd36-a94a8b5b4d15' User entered 'None (0)' | System           | 04 Sep 2020 13:46:04 |
|  | System           | 04 Sep 2020 13:46:04 |



**US3902021**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 10:17:24**

**FATIGUE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-09-04T09:45:47', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: 'ee0d9fb8-1773-47c7-bd36-a94a8b5b4d15' User entered 'None (0)' | System           | 04 Sep 2020 13:46:04 |
|  | System           | 04 Sep 2020 13:46:04 |

**US3902021**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 10:17:24**

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-09-04T09:45:49', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: 'ee0d9fb8-1773-47c7-bd36-a94a8b5b4d15' User entered 'None (0)' | System           | 04 Sep 2020 13:46:04 |
|  | System           | 04 Sep 2020 13:46:04 |

US3902021

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 10:17:24

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-09-04T09:45:51', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: 'ee0d9fb8-1773-47c7-bd36-a94a8b5b4d15' User entered 'None (0)' | System           | 04 Sep 2020 13:46:04 |
|  | System           | 04 Sep 2020 13:46:04 |

**US3902021**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 10:17:24**

**NAUSEA/VOMITING**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-09-04T09:45:53', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: 'ee0d9fb8-1773-47c7-bd36-a94a8b5b4d15' User entered 'None (0)' | System           | 04 Sep 2020 13:46:04 |
|  | System           | 04 Sep 2020 13:46:04 |

**US3902021**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 10:17:24**

**CHILLS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-09-04T09:45:55', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: 'ee0d9fb8-1773-47c7-bd36-a94a8b5b4d15' User entered 'None (0)' | System           | 04 Sep 2020 13:46:04 |
|  | System           | 04 Sep 2020 13:46:04 |

US3902021

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 10:17:24

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) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-09-04T09:45:58', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: 'ee0d9fb8-1773-47c7-bd36-a94a8b5b4d15' User entered 'No (N)' | System           | 04 Sep 2020 13:46:04 |
|  | System           | 04 Sep 2020 13:46:04 |

**US3902021**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 10:17:24**

[PC Time stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-09-04T09:46:01', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: 'ee0d9fb8-1773-47c7-bd36-a94a8b5b4d15' User entered '04 Sep 2020 09:46' | System           | 04 Sep 2020 13:46:04 |
|   | System           | 04 Sep 2020 13:46:04 |

**US3902021**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 10:17:24**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| User entered '03 Sep 2020 12:00' | System           | 02 Sep 2020 22:51:19 |



**US3902021**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 10:17:24**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| User entered '04 Sep 2020 11:59' | System           | 02 Sep 2020 22:51:19 |

**US3902021**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 10:17:24**

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| Data entry locked.   | System           | 02 Sep 2020 22:51:19 |
| User entered 'Day 3' | System           | 02 Sep 2020 22:51:19 |

**US3902021**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 10:17:24**

**HEADACHE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-09-05T09:22:52', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: 'f72975ad-53f8-458d-b12e-9c2eb47f30de' User entered 'None (0)' | System           | 05 Sep 2020 13:23:09 |
|  | System           | 05 Sep 2020 13:23:09 |

**US3902021**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 10:17:24**

**FATIGUE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-09-05T09:22:54', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: 'f72975ad-53f8-458d-b12e-9c2eb47f30de' User entered 'None (0)' | System           | 05 Sep 2020 13:23:09 |
|  | System           | 05 Sep 2020 13:23:09 |

**US3902021**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 10:17:24**

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-09-05T09:22:55', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: 'f72975ad-53f8-458d-b12e-9c2eb47f30de' User entered 'None (0)' | System           | 05 Sep 2020 13:23:09 |
|  | System           | 05 Sep 2020 13:23:09 |

US3902021

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 10:17:24

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-09-05T09:22:57', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: 'f72975ad-53f8-458d-b12e-9c2eb47f30de' User entered 'None (0)' | System           | 05 Sep 2020 13:23:09 |
|  | System           | 05 Sep 2020 13:23:09 |

**US3902021**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 10:17:24**

**NAUSEA/VOMITING**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-09-05T09:22:59', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: 'f72975ad-53f8-458d-b12e-9c2eb47f30de' User entered 'None (0)' | System           | 05 Sep 2020 13:23:09 |
|  | System           | 05 Sep 2020 13:23:09 |

**US3902021**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 10:17:24**

**CHILLS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-09-05T09:23:01', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: 'f72975ad-53f8-458d-b12e-9c2eb47f30de' User entered 'None (0)' | System           | 05 Sep 2020 13:23:09 |
|  | System           | 05 Sep 2020 13:23:09 |



US3902021

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 10:17:24

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) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-09-05T09:23:05', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: 'f72975ad-53f8-458d-b12e-9c2eb47f30de' User entered 'No (N)' | System           | 05 Sep 2020 13:23:09 |
|  | System           | 05 Sep 2020 13:23:09 |

**US3902021**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 10:17:24**

[PC Time stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-09-05T09:23:07', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: 'f72975ad-53f8-458d-b12e-9c2eb47f30de' User entered '05 Sep 2020 09:23' | System           | 05 Sep 2020 13:23:09 |
|   | System           | 05 Sep 2020 13:23:09 |

**US3902021**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 10:17:24**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| User entered '04 Sep 2020 12:00' | System           | 02 Sep 2020 22:51:19 |

**US3902021**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 10:17:24**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| User entered '05 Sep 2020 11:59' | System           | 02 Sep 2020 22:51:19 |

**US3902021**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 10:17:24**

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| Data entry locked.   | System           | 02 Sep 2020 22:51:19 |
| User entered 'Day 4' | System           | 02 Sep 2020 22:51:19 |

**US3902021**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 10:17:24**

**HEADACHE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-09-06T09:41:32', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '9f462609-369b-4df7-8686-d76adad5e9cf' User entered 'None (0)' | System           | 06 Sep 2020 13:42:26 |
|  | System           | 06 Sep 2020 13:42:26 |

**US3902021**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 10:17:24**

**FATIGUE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-09-06T09:41:35', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '9f462609-369b-4df7-8686-d76adad5e9cf' User entered 'None (0)' | System           | 06 Sep 2020 13:42:26 |
|  | System           | 06 Sep 2020 13:42:26 |

**US3902021**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 10:17:24**

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-09-06T09:41:41', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '9f462609-369b-4df7-8686-d76adad5e9cf' User entered 'None (0)' | System           | 06 Sep 2020 13:42:26 |
|  | System           | 06 Sep 2020 13:42:26 |



US3902021

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 10:17:24

**JOINT ACHES IN SEVERAL JOINTS**

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-09-06T09:42:03', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '9f462609-369b-4df7-8686-d76adad5e9cf' User entered 'Some interference with activity (2)' | System           | 06 Sep 2020 13:42:26 |
|   | System           | 06 Sep 2020 13:42:26 |

**US3902021**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 10:17:24**

**NAUSEA/VOMITING**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-09-06T09:42:09', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '9f462609-369b-4df7-8686-d76adad5e9cf' User entered 'None (0)' | System           | 06 Sep 2020 13:42:26 |
|  | System           | 06 Sep 2020 13:42:26 |

**US3902021**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 10:17:24**

**CHILLS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-09-06T09:42:12', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '9f462609-369b-4df7-8686-d76adad5e9cf' User entered 'None (0)' | System           | 06 Sep 2020 13:42:26 |
|  | System           | 06 Sep 2020 13:42:26 |

US3902021

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 10:17:24

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) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-09-06T09:42:18', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '9f462609-369b-4df7-8686-d76adad5e9cf' User entered 'No (N)' | System           | 06 Sep 2020 13:42:26 |
|  | System           | 06 Sep 2020 13:42:26 |

**US3902021**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 10:17:24**

[PC Time stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-09-06T09:42:22', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '9f462609-369b-4df7-8686-d76adad5e9cf' User entered '06 Sep 2020 09:42' | System           | 06 Sep 2020 13:42:26 |
|   | System           | 06 Sep 2020 13:42:26 |

**US3902021**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 10:17:24**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| User entered '05 Sep 2020 12:00' | System           | 02 Sep 2020 22:51:19 |

**US3902021**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 10:17:24**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| User entered '06 Sep 2020 11:59' | System           | 02 Sep 2020 22:51:19 |

**US3902021**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 10:17:24**

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| Data entry locked.   | System           | 02 Sep 2020 22:51:19 |
| User entered 'Day 5' | System           | 02 Sep 2020 22:51:19 |



**US3902021**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 10:17:24**

**HEADACHE**

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
|                   |                  |                      |

US3902021

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 10:17:24

**FATIGUE**

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
|                   |                  |                      |

US3902021

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 10:17:24

**MUSCLE ACHES ALL OVER BODY**

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
|                   |                  |                      |

US3902021

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 10:17:24

**JOINT ACHES IN SEVERAL JOINTS**

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
|                   |                  |                      |

**US3902021**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 10:17:24**

**NAUSEA/VOMITING**

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
|                   |                  |                      |

**US3902021**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 10:17:24**

**CHILLS**

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
|                   |                  |                      |

US3902021

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 10:17:24

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) | 27 Mar 2021 19:18:00 |
|                   |                  |                      |

US3902021

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 10:17:24

[PC Time stamp](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
|                   |                  |                      |



**US3902021**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 10:17:24**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| User entered '06 Sep 2020 12:00' | System           | 02 Sep 2020 22:51:19 |

**US3902021**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 10:17:24**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| User entered '07 Sep 2020 11:59' | System           | 02 Sep 2020 22:51:19 |

**US3902021**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 10:17:24**

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| Data entry locked.   | System           | 02 Sep 2020 22:51:19 |
| User entered 'Day 6' | System           | 02 Sep 2020 22:51:19 |

**US3902021**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 10:17:24**

**HEADACHE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-09-07T12:41:33', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '077225d9-28f4-46d9-8d61-b3e6e3008d3a' User entered 'None (0)' | System           | 07 Sep 2020 16:41:56 |
|  | System           | 07 Sep 2020 16:41:56 |

**US3902021**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 10:17:24**

**FATIGUE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-09-07T12:41:35', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '077225d9-28f4-46d9-8d61-b3e6e3008d3a' User entered 'None (0)' | System           | 07 Sep 2020 16:41:56 |
|  | System           | 07 Sep 2020 16:41:56 |

**US3902021**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 10:17:24**

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-09-07T12:41:38', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '077225d9-28f4-46d9-8d61-b3e6e3008d3a' User entered 'None (0)' | System           | 07 Sep 2020 16:41:56 |
|  | System           | 07 Sep 2020 16:41:56 |

**US3902021**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 10:17:24**

**JOINT ACHES IN SEVERAL JOINTS**

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-09-07T12:41:47', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '077225d9-28f4-46d9-8d61-b3e6e3008d3a' User entered 'Some interference with activity (2)' | System           | 07 Sep 2020 16:41:56 |
|   | System           | 07 Sep 2020 16:41:56 |

**US3902021**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 10:17:24**

**NAUSEA/VOMITING**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-09-07T12:41:48', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '077225d9-28f4-46d9-8d61-b3e6e3008d3a' User entered 'None (0)' | System           | 07 Sep 2020 16:41:56 |
|  | System           | 07 Sep 2020 16:41:56 |



**US3902021**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 10:17:24**

**CHILLS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-09-07T12:41:50', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '077225d9-28f4-46d9-8d61-b3e6e3008d3a' User entered 'None (0)' | System           | 07 Sep 2020 16:41:56 |
|  | System           | 07 Sep 2020 16:41:56 |

US3902021

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 10:17:24

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) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-09-07T12:41:52', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '077225d9-28f4-46d9-8d61-b3e6e3008d3a' User entered 'No (N)' | System           | 07 Sep 2020 16:41:56 |
|  | System           | 07 Sep 2020 16:41:56 |

**US3902021**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 10:17:24**

[PC Time stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-09-07T12:41:54', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '077225d9-28f4-46d9-8d61-b3e6e3008d3a' User entered '07 Sep 2020 12:41' | System           | 07 Sep 2020 16:41:56 |
|   | System           | 07 Sep 2020 16:41:56 |

**US3902021**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 10:17:24**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| User entered '07 Sep 2020 12:00' | System           | 02 Sep 2020 22:51:19 |

**US3902021**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 10:17:24**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| User entered '08 Sep 2020 11:59' | System           | 02 Sep 2020 22:51:19 |

**US3902021**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 10:17:24**

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| Data entry locked.   | System           | 02 Sep 2020 22:51:19 |
| User entered 'Day 7' | System           | 02 Sep 2020 22:51:19 |

**US3902021**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 10:17:24**

**HEADACHE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-09-09T09:36:40', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '72395e78-db85-4c50-a02f-c0ba884d5349' User entered 'None (0)' | System           | 09 Sep 2020 13:37:03 |
|  | System           | 09 Sep 2020 13:37:03 |

**US3902021**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 10:17:24**

**FATIGUE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-09-09T09:36:41', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '72395e78-db85-4c50-a02f-c0ba884d5349' User entered 'None (0)' | System           | 09 Sep 2020 13:37:03 |
|  | System           | 09 Sep 2020 13:37:03 |



US3902021

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 10:17:24

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-09-09T09:36:45', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '72395e78-db85-4c50-a02f-c0ba884d5349' User entered 'None (0)' | System           | 09 Sep 2020 13:37:03 |
|  | System           | 09 Sep 2020 13:37:03 |

**US3902021**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 10:17:24**

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-09-09T09:36:48', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '72395e78-db85-4c50-a02f-c0ba884d5349' | System           | 09 Sep 2020 13:37:03 |
| User entered 'Some interference with activity (2)'   | System           | 09 Sep 2020 13:37:03 |

US3902021

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 10:17:24

**NAUSEA/VOMITING**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-09-09T09:36:50', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '72395e78-db85-4c50-a02f-c0ba884d5349' User entered 'None (0)' | System           | 09 Sep 2020 13:37:03 |
|  | System           | 09 Sep 2020 13:37:03 |

**US3902021**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 10:17:24**

**CHILLS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-09-09T09:36:51', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '72395e78-db85-4c50-a02f-c0ba884d5349' User entered 'None (0)' | System           | 09 Sep 2020 13:37:03 |
|  | System           | 09 Sep 2020 13:37:03 |

US3902021

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 10:17:24

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) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-09-09T09:36:55', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '72395e78-db85-4c50-a02f-c0ba884d5349' User entered 'No (N)' | System           | 09 Sep 2020 13:37:03 |
|  | System           | 09 Sep 2020 13:37:03 |

**US3902021**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 10:17:24**

[PC Time stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-09-09T09:37:00', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '72395e78-db85-4c50-a02f-c0ba884d5349' User entered '09 Sep 2020 09:37' | System           | 09 Sep 2020 13:37:03 |
|   | System           | 09 Sep 2020 13:37:03 |

**US3902021**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 10:17:24**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| User entered '08 Sep 2020 12:00' | System           | 02 Sep 2020 22:51:19 |

**US3902021**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 10:17:24**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| User entered '09 Sep 2020 11:59' | System           | 02 Sep 2020 22:51:19 |



**US3902021**

**Folder: Diary Dose 1 (1)**

**Form: JointsAche\_Day(8)**

**Generated On: 10 Jun 2021 10:17:24**

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| Data entry locked.   | System           | 07 Sep 2020 16:41:56 |
| User entered 'Day 8' | System           | 07 Sep 2020 16:41:56 |

US3902021

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(8)

Generated On: 10 Jun 2021 10:17:24

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) | 27 Mar 2021 19:18:00 |
|                   |                  |                      |

**US3902021**

**Folder: Diary Dose 1 (1)**

**Form: JointsAche\_Day(8)**

**Generated On: 10 Jun 2021 10:17:24**

[PC Time stamp](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
|                   |                  |                      |

**US3902021**

**Folder: Diary Dose 1 (1)**

**Form: JointsAche\_Day(8)**

**Generated On: 10 Jun 2021 10:17:24**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| User entered '09 Sep 2020 12:00' | System           | 07 Sep 2020 16:41:56 |

**US3902021**

**Folder: Diary Dose 1 (1)**

**Form: JointsAche\_Day(8)**

**Generated On: 10 Jun 2021 10:17:24**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| User entered '10 Sep 2020 11:59' | System           | 07 Sep 2020 16:41:56 |

**US3902021**

**Folder: Diary Dose 1 (1)**

**Form: JointsAche\_Day(9)**

**Generated On: 10 Jun 2021 10:17:24**

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| Data entry locked.   | System           | 09 Sep 2020 13:37:03 |
| User entered 'Day 9' | System           | 09 Sep 2020 13:37:03 |

**US3902021**

**Folder: Diary Dose 1 (1)**

**Form: JointsAche\_Day(9)**

**Generated On: 10 Jun 2021 10:17:24**

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) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-09-11T09:31:30', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: 'bcffd06b-7800-41e5-904a-ea25ccec3fad' | System           | 11 Sep 2020 13:31:35 |
| User entered 'Some interference with activity (2)'   | System           | 11 Sep 2020 13:31:35 |

**US3902021**

**Folder: Diary Dose 1 (1)**

**Form: JointsAche\_Day(9)**

**Generated On: 10 Jun 2021 10:17:24**

[PC Time stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-09-11T09:31:32', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: 'bcffd06b-7800-41e5-904a-ea25ccec3fad' User entered '11 Sep 2020 09:31' | System           | 11 Sep 2020 13:31:35 |
|   | System           | 11 Sep 2020 13:31:35 |



**US3902021**

**Folder: Diary Dose 1 (1)**

**Form: JointsAche\_Day(9)**

**Generated On: 10 Jun 2021 10:17:24**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| User entered '10 Sep 2020 12:00' | System           | 09 Sep 2020 13:37:03 |

**US3902021**

**Folder: Diary Dose 1 (1)**

**Form: JointsAche\_Day(9)**

**Generated On: 10 Jun 2021 10:17:24**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| User entered '11 Sep 2020 11:59' | System           | 09 Sep 2020 13:37:03 |

**US3902021**

**Folder: Diary Dose 1 (1)**

**Form: JointsAche\_Day(10)**

**Generated On: 10 Jun 2021 10:17:24**

**TIMEPOINT**

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| Data hard locked.     | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| Data entry locked.    | System           | 11 Sep 2020 13:31:35 |
| User entered 'Day 10' | System           | 11 Sep 2020 13:31:35 |

US3902021

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(10)

Generated On: 10 Jun 2021 10:17:24

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) | 27 Mar 2021 19:18:00 |
|                   |                  |                      |

**US3902021**

**Folder: Diary Dose 1 (1)**

**Form: JointsAche\_Day(10)**

**Generated On: 10 Jun 2021 10:17:24**

[PC Time stamp](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
|                   |                  |                      |

**US3902021**

**Folder: Diary Dose 1 (1)**

**Form: JointsAche\_Day(10)**

**Generated On: 10 Jun 2021 10:17:24**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| User entered '11 Sep 2020 12:00' | System           | 11 Sep 2020 13:31:35 |

**US3902021**

**Folder: Diary Dose 1 (1)**

**Form: JointsAche\_Day(10)**

**Generated On: 10 Jun 2021 10:17:24**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| User entered '12 Sep 2020 11:59' | System           | 11 Sep 2020 13:31:35 |

**US3902021**

**Folder: Diary Dose 1 (1)**

**Form: JointsAche\_Day(11)**

**Generated On: 10 Jun 2021 10:17:24**

**TIMEPOINT**

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| Data hard locked.     | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| Data entry locked.    | System           | 11 Sep 2020 13:31:35 |
| User entered 'Day 11' | System           | 11 Sep 2020 13:31:35 |



US3902021

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(11)

Generated On: 10 Jun 2021 10:17:24

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) | 27 Mar 2021 19:18:00 |
|                   |                  |                      |

**US3902021**

**Folder: Diary Dose 1 (1)**

**Form: JointsAche\_Day(11)**

**Generated On: 10 Jun 2021 10:17:24**

[PC Time stamp](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
|                   |                  |                      |

**US3902021**

**Folder: Diary Dose 1 (1)**

**Form: JointsAche\_Day(11)**

**Generated On: 10 Jun 2021 10:17:24**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| User entered '12 Sep 2020 12:00' | System           | 11 Sep 2020 13:31:35 |

**US3902021**

**Folder: Diary Dose 1 (1)**

**Form: JointsAche\_Day(11)**

**Generated On: 10 Jun 2021 10:17:24**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| User entered '13 Sep 2020 11:59' | System           | 11 Sep 2020 13:31:35 |

**US3902021**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(8)**

**Generated On: 10 Jun 2021 10:17:24**

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| Data entry locked.   | System           | 07 Sep 2020 16:41:56 |
| User entered 'Day 8' | System           | 07 Sep 2020 16:41:56 |

US3902021

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 10 Jun 2021 10:17:24

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) | 27 Mar 2021 19:18:00 |
|                   |                  |                      |

**US3902021**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(8)**

**Generated On: 10 Jun 2021 10:17:24**

[PC Time stamp](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
|                   |                  |                      |

**US3902021**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(8)**

**Generated On: 10 Jun 2021 10:17:24**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| User entered '09 Sep 2020 12:00' | System           | 07 Sep 2020 16:41:56 |



**US3902021**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(8)**

**Generated On: 10 Jun 2021 10:17:24**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| User entered '10 Sep 2020 11:59' | System           | 07 Sep 2020 16:41:56 |

**US3902021**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(9)**

**Generated On: 10 Jun 2021 10:17:24**

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| Data entry locked.   | System           | 09 Sep 2020 13:37:03 |
| User entered 'Day 9' | System           | 09 Sep 2020 13:37:03 |

US3902021

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(9)

Generated On: 10 Jun 2021 10:17:24

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) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-09-11T09:31:39', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: 'c1a19ee9-91af-4189-9dd8-cd2b4be02bb6' User entered 'No (N)' | System           | 11 Sep 2020 13:31:43 |
|  | System           | 11 Sep 2020 13:31:43 |

**US3902021**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(9)**

**Generated On: 10 Jun 2021 10:17:24**

[PC Time stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-09-11T09:31:41', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: 'c1a19ee9-91af-4189-9dd8-cd2b4be02bb6' User entered '11 Sep 2020 09:31' | System           | 11 Sep 2020 13:31:43 |
|   | System           | 11 Sep 2020 13:31:43 |

**US3902021**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(9)**

**Generated On: 10 Jun 2021 10:17:24**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| User entered '10 Sep 2020 12:00' | System           | 09 Sep 2020 13:37:03 |

**US3902021**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(9)**

**Generated On: 10 Jun 2021 10:17:24**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| User entered '11 Sep 2020 11:59' | System           | 09 Sep 2020 13:37:03 |

**US3902021**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(10)**

**Generated On: 10 Jun 2021 10:17:24**

**TIMEPOINT**

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| Data hard locked.     | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| Data entry locked.    | System           | 11 Sep 2020 13:31:35 |
| User entered 'Day 10' | System           | 11 Sep 2020 13:31:35 |

US3902021

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(10)

Generated On: 10 Jun 2021 10:17:24

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) | 27 Mar 2021 19:18:00 |
|                   |                  |                      |



**US3902021**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(10)**

**Generated On: 10 Jun 2021 10:17:24**

[PC Time stamp](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
|                   |                  |                      |

**US3902021**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(10)**

**Generated On: 10 Jun 2021 10:17:24**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| User entered '11 Sep 2020 12:00' | System           | 11 Sep 2020 13:31:35 |

**US3902021**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(10)**

**Generated On: 10 Jun 2021 10:17:24**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| User entered '12 Sep 2020 11:59' | System           | 11 Sep 2020 13:31:35 |

**US3902021**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(11)**

**Generated On: 10 Jun 2021 10:17:24**

**TIMEPOINT**

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| Data hard locked.     | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| Data entry locked.    | System           | 11 Sep 2020 13:31:35 |
| User entered 'Day 11' | System           | 11 Sep 2020 13:31:35 |

US3902021

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(11)

Generated On: 10 Jun 2021 10:17:24

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) | 27 Mar 2021 19:18:00 |
|                   |                  |                      |

**US3902021**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(11)**

**Generated On: 10 Jun 2021 10:17:24**

[PC Time stamp](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
|                   |                  |                      |

**US3902021**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(11)**

**Generated On: 10 Jun 2021 10:17:24**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| User entered '12 Sep 2020 12:00' | System           | 11 Sep 2020 13:31:35 |

**US3902021**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(11)**

**Generated On: 10 Jun 2021 10:17:24**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| User entered '13 Sep 2020 11:59' | System           | 11 Sep 2020 13:31:35 |



**US3902021**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 10:17:24**

[Was Contact Attempted?](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 14 Apr 2021 06:18:15 |
| User signature succeeded. | Murray Kimmel (b) (4) | 30 Mar 2021 18:10:57 |
| User entered 'Yes (Y)'    | (b) (4), (b) (6)      | 16 Sep 2020 18:49:04 |

**US3902021**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 10:17:24**

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

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 14 Apr 2021 06:18:15 |
| User signature succeeded. | Murray Kimmel (b) (4) | 30 Mar 2021 18:10:57 |
| User entered '9 Sep 2020' | (b) (4), (b) (6)      | 16 Sep 2020 18:49:04 |

**US3902021**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 10:17:24**

[Please select one status for the follow-up contact](#)

| Audit                                      | User                  | Time (GMT)           |
|--|-----------------------|----------------------|
| Data hard locked.                          | (b) (4), (b) (6)      | 14 Apr 2021 06:18:15 |
| User signature succeeded.                  | Murray Kimmel (b) (4) | 30 Mar 2021 18:10:57 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4), (b) (6)      | 16 Sep 2020 18:49:04 |

**US3902021**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 10:17:24**

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 14 Apr 2021 06:18:15 |
| User signature succeeded. | Murray Kimmel (b) (4) | 30 Mar 2021 18:10:57 |
| User entered empty.       | (b) (4), (b) (6)      | 16 Sep 2020 18:49:04 |

**US3902021**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 10:17:24**

[Is the participant continuing to the next visit?](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 14 Apr 2021 06:18:15 |
| User signature succeeded. | Murray Kimmel (b) (4) | 30 Mar 2021 18:10:57 |
| User entered 'Yes (Y)'    | (b) (4), (b) (6)      | 16 Sep 2020 18:49:11 |

**US3902021**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 10:17:24**

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 06:18:15 |
| User entered 'I'  | System           | 16 Sep 2020 18:49:11 |

**US3902021**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 10:17:24**

[Was Contact Attempted?](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 14 Apr 2021 06:18:15 |
| User signature succeeded. | Murray Kimmel (b) (4) | 30 Mar 2021 18:10:57 |
| User entered 'Yes (Y)'    | (b) (4), (b) (6)      | 16 Sep 2020 18:49:27 |

**US3902021**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 10:17:24**

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

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 14 Apr 2021 06:18:15 |
| User signature succeeded.  | Murray Kimmel (b) (4) | 30 Mar 2021 18:10:57 |
| User entered '16 Sep 2020' | (b) (4), (b) (6)      | 16 Sep 2020 18:49:27 |



**US3902021**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 10:17:24**

[Please select one status for the follow-up contact](#)

| Audit                                      | User                  | Time (GMT)           |
|--|-----------------------|----------------------|
| Data hard locked.                          | (b) (4), (b) (6)      | 14 Apr 2021 06:18:15 |
| User signature succeeded.                  | Murray Kimmel (b) (4) | 30 Mar 2021 18:10:57 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4), (b) (6)      | 16 Sep 2020 18:49:27 |

**US3902021**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 10:17:24**

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 14 Apr 2021 06:18:15 |
| User signature succeeded. | Murray Kimmel (b) (4) | 30 Mar 2021 18:10:57 |
| User entered empty.       | (b) (4), (b) (6)      | 16 Sep 2020 18:49:27 |

**US3902021**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 10:17:24**

[Is the participant continuing to the next visit?](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 14 Apr 2021 06:18:15 |
| User signature succeeded. | Murray Kimmel (b) (4) | 30 Mar 2021 18:10:57 |
| User entered 'Yes (Y)'    | (b) (4), (b) (6)      | 16 Sep 2020 18:49:36 |

**US3902021**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 10:17:24**

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 06:18:15 |
| User entered 'I'  | System           | 16 Sep 2020 18:49:36 |

**US3902021**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 10:17:24**

[Was Contact Attempted?](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 14 Apr 2021 06:18:15 |
| User signature succeeded. | Murray Kimmel (b) (4)   | 30 Mar 2021 18:10:57 |
| User entered 'Yes (Y)'    | Taylor Atkinson (b) (4) | 29 Sep 2020 21:44:07 |

**US3902021**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 10:17:24**

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

| Audit                      | User                    | Time (GMT)           |
|----------------------------|-------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)        | 14 Apr 2021 06:18:15 |
| User signature succeeded.  | Murray Kimmel (b) (4)   | 30 Mar 2021 18:10:57 |
| User entered '23 Sep 2020' | Taylor Atkinson (b) (4) | 29 Sep 2020 21:44:07 |

**US3902021**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 10:17:24**

[Please select one status for the follow-up contact](#)

| Audit                                      | User                    | Time (GMT)           |
|--|-------------------------|----------------------|
| Data hard locked.                          | (b) (4), (b) (6)        | 14 Apr 2021 06:18:15 |
| User signature succeeded.                  | Murray Kimmel (b) (4)   | 30 Mar 2021 18:10:57 |
| User entered 'Contact Made (CONTACT MADE)' | Taylor Atkinson (b) (4) | 29 Sep 2020 21:44:07 |

US3902021

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:17:24

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 14 Apr 2021 06:18:15 |
| User signature succeeded. | Murray Kimmel (b) (4)   | 30 Mar 2021 18:10:57 |
| User entered empty.       | Taylor Atkinson (b) (4) | 29 Sep 2020 21:44:07 |



**US3902021**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 10:17:24**

[Is the participant continuing to the next visit?](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 14 Apr 2021 06:18:15 |
| User signature succeeded. | Murray Kimmel (b) (4)   | 30 Mar 2021 18:10:57 |
| User entered 'Yes (Y)'    | Taylor Atkinson (b) (4) | 29 Sep 2020 21:44:17 |

**US3902021**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 10:17:24**

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 06:18:15 |
| User entered 'I'  | System           | 29 Sep 2020 21:44:17 |

**US3902021**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 10:17:24**

[Was this visit performed?](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 14 Apr 2021 06:18:15 |
| User signature succeeded. | Murray Kimmel (b) (4) | 30 Mar 2021 18:11:36 |
| User entered 'Yes (Y)'    | Bram Swarr (b) (4)    | 13 Oct 2020 19:47:42 |

**US3902021**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 10:17:24**

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

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 14 Apr 2021 06:18:15 |
| User signature succeeded.  | Murray Kimmel (b) (4) | 30 Mar 2021 18:11:36 |
| User entered '29 Sep 2020' | Bram Swarr (b) (4)    | 13 Oct 2020 19:47:42 |

**US3902021**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 10:17:24**

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

| Audit                          | User                  | Time (GMT)           |
|--------------------------------|-----------------------|----------------------|
| Data hard locked.              | (b) (4), (b) (6)      | 14 Apr 2021 06:18:15 |
| User signature succeeded.      | Murray Kimmel (b) (4) | 30 Mar 2021 18:11:36 |
| User entered 'Clinic (Clinic)' | Bram Swarr (b) (4)    | 13 Oct 2020 19:47:42 |

**US3902021**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 10:17:24**

[Folder OID](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| Data hard locked.     | (b) (4), (b) (6) | 14 Apr 2021 06:18:15 |
| User entered 'VISIT2' | System           | 13 Oct 2020 19:47:42 |

US3902021

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:17:24

[Timepoint](#)

| Audit  | User               | Time (GMT)           |
|--|--------------------|----------------------|
| Data hard locked.                                | (b) (4), (b) (6)   | 14 Apr 2021 06:18:15 |
| User accepted default value 'Pre-Dose (PREDOSE)' | Bram Swarr (b) (4) | 13 Oct 2020 19:49:58 |

US3902021

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:17:24

[Were vital signs assessed?](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 14 Apr 2021 06:18:15 |
| User signature succeeded. | Murray Kimmel (b) (4) | 30 Mar 2021 18:11:36 |
| User entered 'Yes (Y)'    | Bram Swarr (b) (4)    | 13 Oct 2020 19:49:58 |



**US3902021**

**Folder: Visit 2 Day 29 (1)**

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

**Generated On: 10 Jun 2021 10:17:24**

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

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 14 Apr 2021 06:18:15 |
| User signature succeeded.  | Murray Kimmel (b) (4) | 30 Mar 2021 18:11:36 |
| User entered '29 Sep 2020' | Bram Swarr (b) (4)    | 13 Oct 2020 19:49:58 |

**US3902021**

**Folder: Visit 2 Day 29 (1)**

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

**Generated On: 10 Jun 2021 10:17:24**

**Time of assessment (00:00-23:59)**

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 14 Apr 2021 06:18:15 |
| User signature succeeded. | Murray Kimmel (b) (4) | 30 Mar 2021 18:11:36 |
| User entered '15:18'      | Bram Swarr (b) (4)    | 13 Oct 2020 19:49:58 |

**US3902021**

**Folder: Visit 2 Day 29 (1)**

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

**Generated On: 10 Jun 2021 10:17:24**

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

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 14 Apr 2021 06:18:15 |
| User entered '29 Sep 2020 15:18' | System           | 13 Oct 2020 19:49:58 |

US3902021

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:17:24

Temperature (xxx.x)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 14 Apr 2021 06:18:15 |
| User signature succeeded. | Murray Kimmel (b) (4) | 30 Mar 2021 18:11:36 |
| User entered '97.7' F     | Bram Swarr (b) (4)    | 13 Oct 2020 19:49:58 |

**US3902021**

**Folder: Visit 2 Day 29 (1)**

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

**Generated On: 10 Jun 2021 10:17:24**

[Route of measurement](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 14 Apr 2021 06:18:15 |
| User signature succeeded.  | Murray Kimmel (b) (4) | 30 Mar 2021 18:11:36 |
| User entered 'Oral (Oral)' | Bram Swarr (b) (4)    | 13 Oct 2020 19:49:58 |

**US3902021**

**Folder: Visit 2 Day 29 (1)**

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

**Generated On: 10 Jun 2021 10:17:24**

[If Other, specify](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 14 Apr 2021 06:18:15 |
| User signature succeeded. | Murray Kimmel (b) (4) | 30 Mar 2021 18:11:36 |
| User entered empty.       | Bram Swarr (b) (4)    | 13 Oct 2020 19:49:58 |

**US3902021**

**Folder: Visit 2 Day 29 (1)**

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

**Generated On: 10 Jun 2021 10:17:24**

[Pulse \(xxx\)](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 14 Apr 2021 06:18:15 |
| User signature succeeded. | Murray Kimmel (b) (4) | 30 Mar 2021 18:11:36 |
| User entered '71'         | Bram Swarr (b) (4)    | 13 Oct 2020 19:49:58 |

**US3902021**

**Folder: Visit 2 Day 29 (1)**

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

**Generated On: 10 Jun 2021 10:17:24**

[Pulse units](#)

| Audit              | User             | Time (GMT)           |
|--------------------|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 14 Apr 2021 06:18:15 |
| User entered 'bpm' | System           | 13 Oct 2020 19:49:58 |



**US3902021**

**Folder: Visit 2 Day 29 (1)**

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

**Generated On: 10 Jun 2021 10:17:24**

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

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 14 Apr 2021 06:18:15 |
| User signature succeeded. | Murray Kimmel (b) (4) | 30 Mar 2021 18:11:36 |
| User entered '16'         | Bram Swarr (b) (4)    | 13 Oct 2020 19:49:58 |

**US3902021**

**Folder: Visit 2 Day 29 (1)**

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

**Generated On: 10 Jun 2021 10:17:24**

[Respiratory Rate units](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6) | 14 Apr 2021 06:18:15 |
| User entered 'breaths/min' | System           | 13 Oct 2020 19:49:58 |

**US3902021**

**Folder: Visit 2 Day 29 (1)**

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

**Generated On: 10 Jun 2021 10:17:24**

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

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 14 Apr 2021 06:18:15 |
| User signature succeeded. | Murray Kimmel (b) (4) | 30 Mar 2021 18:11:36 |
| User entered '108'        | Bram Swarr (b) (4)    | 13 Oct 2020 19:49:58 |

**US3902021**

**Folder: Visit 2 Day 29 (1)**

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

**Generated On: 10 Jun 2021 10:17:24**

[Systolic Blood Pressure units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 14 Apr 2021 06:18:15 |
| User entered 'mmHg' | System           | 13 Oct 2020 19:49:58 |

**US3902021**

**Folder: Visit 2 Day 29 (1)**

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

**Generated On: 10 Jun 2021 10:17:24**

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

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 14 Apr 2021 06:18:15 |
| User signature succeeded. | Murray Kimmel (b) (4) | 30 Mar 2021 18:11:36 |
| User entered '72'         | Bram Swarr (b) (4)    | 13 Oct 2020 19:49:58 |

**US3902021**

**Folder: Visit 2 Day 29 (1)**

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

**Generated On: 10 Jun 2021 10:17:24**

[Diastolic Blood Pressure units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 14 Apr 2021 06:18:15 |
| User entered 'mmHg' | System           | 13 Oct 2020 19:49:58 |

US3902021

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:17:24

[Timepoint](#)

| Audit  | User               | Time (GMT)           |
|--|--------------------|----------------------|
| Data hard locked.                                  | (b) (4), (b) (6)   | 14 Apr 2021 06:18:15 |
| User accepted default value 'Post-Dose (POSTDOSE)' | Bram Swarr (b) (4) | 13 Oct 2020 19:49:58 |

US3902021

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:17:24

[Were vital signs assessed?](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 14 Apr 2021 06:18:15 |
| User signature succeeded. | Murray Kimmel (b) (4) | 30 Mar 2021 18:11:36 |
| User entered 'Yes (Y)'    | Bram Swarr (b) (4)    | 13 Oct 2020 19:49:58 |



**US3902021**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 10:17:24**

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

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 14 Apr 2021 06:18:15 |
| User signature succeeded.  | Murray Kimmel (b) (4) | 30 Mar 2021 18:11:36 |
| User entered '29 Sep 2020' | Bram Swarr (b) (4)    | 13 Oct 2020 19:49:58 |

**US3902021**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 10:17:24**

**Time of assessment (00:00-23:59)**

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 14 Apr 2021 06:18:15 |
| User signature succeeded. | Murray Kimmel (b) (4) | 30 Mar 2021 18:11:36 |
| User entered '17:40'      | Bram Swarr (b) (4)    | 13 Oct 2020 19:49:58 |

**US3902021**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 10:17:24**

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

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 14 Apr 2021 06:18:15 |
| User entered '29 Sep 2020 17:40' | System           | 13 Oct 2020 19:49:58 |

US3902021

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:17:24

Temperature (xxx.x)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 14 Apr 2021 06:18:15 |
| User signature succeeded. | Murray Kimmel (b) (4) | 30 Mar 2021 18:11:36 |
| User entered '97.3' F     | Bram Swarr (b) (4)    | 13 Oct 2020 19:49:58 |

**US3902021**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 10:17:24**

[Route of measurement](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 14 Apr 2021 06:18:15 |
| User signature succeeded.  | Murray Kimmel (b) (4) | 30 Mar 2021 18:11:36 |
| User entered 'Oral (Oral)' | Bram Swarr (b) (4)    | 13 Oct 2020 19:49:58 |

**US3902021**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 10:17:24**

[If Other, specify](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 14 Apr 2021 06:18:15 |
| User signature succeeded. | Murray Kimmel (b) (4) | 30 Mar 2021 18:11:36 |
| User entered empty.       | Bram Swarr (b) (4)    | 13 Oct 2020 19:49:58 |

**US3902021**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 10:17:24**

[Pulse \(xxx\)](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 14 Apr 2021 06:18:15 |
| User signature succeeded. | Murray Kimmel (b) (4) | 30 Mar 2021 18:11:36 |
| User entered '74'         | Bram Swarr (b) (4)    | 13 Oct 2020 19:49:58 |

**US3902021**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 10:17:24**

[Pulse units](#)

| Audit              | User             | Time (GMT)           |
|--------------------|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 14 Apr 2021 06:18:15 |
| User entered 'bpm' | System           | 13 Oct 2020 19:49:58 |



**US3902021**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 10:17:24**

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

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 14 Apr 2021 06:18:15 |
| User signature succeeded. | Murray Kimmel (b) (4) | 30 Mar 2021 18:11:36 |
| User entered '16'         | Bram Swarr (b) (4)    | 13 Oct 2020 19:49:58 |

US3902021

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:17:24

[Respiratory Rate units](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6) | 14 Apr 2021 06:18:15 |
| User entered 'breaths/min' | System           | 13 Oct 2020 19:49:58 |

US3902021

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:17:24

Systolic Blood Pressure (xxx)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 14 Apr 2021 06:18:15 |
| User signature succeeded. | Murray Kimmel (b) (4) | 30 Mar 2021 18:11:36 |
| User entered '105'        | Bram Swarr (b) (4)    | 13 Oct 2020 19:49:58 |

**US3902021**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 10:17:24**

[Systolic Blood Pressure units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 14 Apr 2021 06:18:15 |
| User entered 'mmHg' | System           | 13 Oct 2020 19:49:58 |

US3902021

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:17:24

Diastolic Blood Pressure (xxx)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 14 Apr 2021 06:18:15 |
| User signature succeeded. | Murray Kimmel (b) (4) | 30 Mar 2021 18:11:36 |
| User entered '75'         | Bram Swarr (b) (4)    | 13 Oct 2020 19:49:58 |

**US3902021**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 10:17:24**

[Diastolic Blood Pressure units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 14 Apr 2021 06:18:15 |
| User entered 'mmHg' | System           | 13 Oct 2020 19:49:58 |

US3902021

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:17:24

[Was the physical examination performed?](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 14 Apr 2021 06:18:15 |
| User signature succeeded. | Murray Kimmel (b) (4) | 30 Mar 2021 18:11:36 |
| User entered 'No (N)'     | Bram Swarr (b) (4)    | 13 Oct 2020 19:50:08 |

**US3902021**

**Folder: Visit 2 Day 29 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 10:17:24**

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

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 14 Apr 2021 06:18:15 |
| User signature succeeded. | Murray Kimmel (b) (4) | 30 Mar 2021 18:11:36 |
| User entered empty.       | Bram Swarr (b) (4)    | 13 Oct 2020 19:50:08 |



**US3902021**

**Folder: Visit 2 Day 29 (1)**

**Form: Pregnancy Test**

**Generated On: 10 Jun 2021 10:17:24**

[Was the pregnancy test performed?](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 14 Apr 2021 06:18:15 |
| User signature succeeded. | Murray Kimmel (b) (4) | 30 Mar 2021 18:11:36 |
| User entered 'Yes (Y)'    | Bram Swarr (b) (4)    | 13 Oct 2020 19:50:24 |

**US3902021**

**Folder: Visit 2 Day 29 (1)**

**Form: Pregnancy Test**

**Generated On: 10 Jun 2021 10:17:24**

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

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 14 Apr 2021 06:18:15 |
| User signature succeeded.  | Murray Kimmel (b) (4) | 30 Mar 2021 18:11:36 |
| User entered '29 Sep 2020' | Bram Swarr (b) (4)    | 13 Oct 2020 19:50:24 |

**US3902021**

**Folder: Visit 2 Day 29 (1)**

**Form: Pregnancy Test**

**Generated On: 10 Jun 2021 10:17:24**

[Test performed](#)

| Audit                        | User                  | Time (GMT)           |
|------------------------------|-----------------------|----------------------|
| Data hard locked.            | (b) (4), (b) (6)      | 14 Apr 2021 06:18:15 |
| User signature succeeded.    | Murray Kimmel (b) (4) | 30 Mar 2021 18:11:36 |
| User entered 'Urine (URINE)' | Bram Swarr (b) (4)    | 13 Oct 2020 19:50:24 |

US3902021

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 10:17:24

[Result](#)

| Audit                              | User                  | Time (GMT)           |
|------------------------------------|-----------------------|----------------------|
| Data hard locked.                  | (b) (4), (b) (6)      | 14 Apr 2021 06:18:15 |
| User signature succeeded.          | Murray Kimmel (b) (4) | 30 Mar 2021 18:11:36 |
| User entered 'Negative (NEGATIVE)' | Bram Swarr (b) (4)    | 13 Oct 2020 19:50:24 |

US3902021

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 10:17:24

[Was FSH sample collected?](#)

| Audit   | User                  | Time (GMT)           |
|---|-----------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)      | 14 Apr 2021 06:18:15 |
| User signature succeeded.                                 | Murray Kimmel (b) (4) | 30 Mar 2021 18:11:36 |
| User entered 'No (N)' reason for change: Data Entry Error | Bram Swarr (b) (4)    | 13 Oct 2020 19:50:29 |
| User entered empty.                                       | Bram Swarr (b) (4)    | 13 Oct 2020 19:50:24 |

**US3902021**

**Folder: Visit 2 Day 29 (1)**

**Form: Pregnancy Test**

**Generated On: 10 Jun 2021 10:17:24**

[Collection date](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 14 Apr 2021 06:18:15 |
| User signature succeeded. | Murray Kimmel (b) (4) | 30 Mar 2021 18:11:36 |
| User entered empty.       | Bram Swarr (b) (4)    | 13 Oct 2020 19:50:24 |

**US3902021**

**Folder: Visit 2 Day 29 (1)**

**Form: Pregnancy Test**

**Generated On: 10 Jun 2021 10:17:24**

[Collection time](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 14 Apr 2021 06:18:15 |
| User signature succeeded. | Murray Kimmel (b) (4) | 30 Mar 2021 18:11:36 |
| User entered empty.       | Bram Swarr (b) (4)    | 13 Oct 2020 19:50:24 |

**US3902021**

**Folder: Visit 2 Day 29 (1)**

**Form: Pregnancy Test**

**Generated On: 10 Jun 2021 10:17:24**

[Collection date and time \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 14 Apr 2021 06:18:15 |
| User entered empty. | System           | 13 Oct 2020 19:50:24 |



**US3902021**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 10:17:24**

[Was study treatment given?](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 14 Apr 2021 06:18:15 |
| User signature succeeded. | Murray Kimmel (b) (4)   | 30 Mar 2021 18:11:36 |
| User entered 'Yes (Y)'    | Taylor Atkinson (b) (4) | 29 Sep 2020 21:44:37 |

**US3902021**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 10:17:24**

[If No, reason not given](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 14 Apr 2021 06:18:15 |
| User signature succeeded. | Murray Kimmel (b) (4)   | 30 Mar 2021 18:11:36 |
| User entered empty.       | Taylor Atkinson (b) (4) | 29 Sep 2020 21:44:37 |

US3902021

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:17:24

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)        | 14 Apr 2021 06:18:15 |
| User signature succeeded. | Murray Kimmel (b) (4)   | 30 Mar 2021 18:11:36 |
| User entered empty.       | Taylor Atkinson (b) (4) | 29 Sep 2020 21:44:37 |

**US3902021**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 10:17:24**

[What was the study treatment?](#)

| Audit                               | User             | Time (GMT)           |
|-------------------------------------|------------------|----------------------|
| Data hard locked.                   | (b) (4), (b) (6) | 14 Apr 2021 06:18:15 |
| User entered 'MRNA-1273 OR PLACEBO' | System           | 29 Sep 2020 21:44:37 |

US3902021

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:17:24

What was the treatment date? (dd MMM yyyy)

| Audit                      | User                    | Time (GMT)           |
|----------------------------|-------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)        | 14 Apr 2021 06:18:15 |
| User signature succeeded.  | Murray Kimmel (b) (4)   | 30 Mar 2021 18:11:36 |
| User entered '29 Sep 2020' | Taylor Atkinson (b) (4) | 29 Sep 2020 21:44:37 |

**US3902021**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 10:17:24**

[What was the treatment time? \(00:00-23:59\)](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 14 Apr 2021 06:18:15 |
| User signature succeeded. | Murray Kimmel (b) (4)   | 30 Mar 2021 18:11:36 |
| User entered '17:09'      | Taylor Atkinson (b) (4) | 29 Sep 2020 21:44:37 |

**US3902021**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 10:17:24**

[Treatment Date and Time \(derived\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 14 Apr 2021 06:18:15 |
| User entered '29 Sep 2020 17:09' | System           | 29 Sep 2020 21:44:37 |

US3902021

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:17:24

[Which arm was used to give treatment?](#)

| Audit                              | User                    | Time (GMT)           |
|------------------------------------|-------------------------|----------------------|
| Data hard locked.                  | (b) (4), (b) (6)        | 14 Apr 2021 06:18:15 |
| User signature succeeded.          | Murray Kimmel (b) (4)   | 30 Mar 2021 18:11:36 |
| User entered 'Left Arm (LEFT ARM)' | Taylor Atkinson (b) (4) | 29 Sep 2020 21:44:37 |



US3902021

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:17:24

[What was the frequency of the study treatment dosing?](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 14 Apr 2021 06:18:15 |
| User entered 'ONCE' | System           | 29 Sep 2020 21:44:37 |

US3902021

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:17:24

What was the route of administration for the study treatment?

| Audit                        | User             | Time (GMT)           |
|------------------------------|------------------|----------------------|
| Data hard locked.            | (b) (4), (b) (6) | 14 Apr 2021 06:18:15 |
| User entered 'INTRAMUSCULAR' | System           | 29 Sep 2020 21:44:37 |

**US3902021**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 10:17:24**

[Was the sample collected?](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 14 Apr 2021 06:18:15 |
| User signature succeeded. | Murray Kimmel (b) (4) | 30 Mar 2021 18:11:36 |
| User entered 'Yes (Y)'    | Bram Swarr (b) (4)    | 13 Oct 2020 19:50:41 |

**US3902021**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 10:17:24**

**Collection date** (*dd MMM yyyy*)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 14 Apr 2021 06:18:15 |
| User signature succeeded.  | Murray Kimmel (b) (4) | 30 Mar 2021 18:11:36 |
| User entered '29 Sep 2020' | Bram Swarr (b) (4)    | 13 Oct 2020 19:50:41 |

**US3902021**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 10:17:24**

[Collection time \(00:00-23:59\)](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 14 Apr 2021 06:18:15 |
| User signature succeeded. | Murray Kimmel (b) (4) | 30 Mar 2021 18:11:36 |
| User entered '16:33'      | Bram Swarr (b) (4)    | 13 Oct 2020 19:50:41 |

**US3902021**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 10:17:24**

[Collection date and time \(derived\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 14 Apr 2021 06:18:15 |
| User entered '29 Sep 2020 16:33' | System           | 13 Oct 2020 19:50:41 |

US3902021

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 10:17:24

Collection date (*dd MMM yyyy*)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 14 Apr 2021 06:18:15 |
| User signature succeeded.  | Murray Kimmel (b) (4) | 30 Mar 2021 18:10:57 |
| User entered '29 Sep 2020' | Bram Swarr (b) (4)    | 13 Oct 2020 19:50:58 |

**US3902021**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 10:17:24**

[Lab Test](#)

| Audit  | User               | Time (GMT)           |
|--|--------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)   | 14 Apr 2021 06:18:15 |
| User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)' | Bram Swarr (b) (4) | 13 Oct 2020 19:50:58 |



**US3902021**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 10:17:24**

[Was the sample collected?](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 14 Apr 2021 06:18:15 |
| User signature succeeded. | Murray Kimmel (b) (4) | 30 Mar 2021 18:10:57 |
| User entered 'Yes (Y)'    | Bram Swarr (b) (4)    | 13 Oct 2020 19:50:58 |

**US3902021**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 10:17:24**

[Collection time \(00:00 - 23:59\)](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 14 Apr 2021 06:18:15 |
| User signature succeeded. | Murray Kimmel (b) (4) | 30 Mar 2021 18:10:57 |
| User entered '16:34'      | Bram Swarr (b) (4)    | 13 Oct 2020 19:50:58 |

**US3902021**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 10:17:24**

[Collection date and time \(derived\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 14 Apr 2021 06:18:15 |
| User entered '29 Sep 2020 16:34' | System           | 13 Oct 2020 19:50:58 |

**US3902021**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 10:17:24**

[Lab Test](#)

| Audit  | User               | Time (GMT)           |
|--|--------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)   | 14 Apr 2021 06:18:15 |
| User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)' | Bram Swarr (b) (4) | 13 Oct 2020 19:50:58 |

**US3902021**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 10:17:24**

[Was the sample collected?](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 14 Apr 2021 06:18:15 |
| User signature succeeded. | Murray Kimmel (b) (4) | 30 Mar 2021 18:10:57 |
| User entered 'No (N)'     | Bram Swarr (b) (4)    | 13 Oct 2020 19:50:58 |

**US3902021**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 10:17:24**

[Collection time \(00:00 - 23:59\)](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 14 Apr 2021 06:18:15 |
| User signature succeeded. | Murray Kimmel (b) (4) | 30 Mar 2021 18:10:57 |
| User entered empty.       | Bram Swarr (b) (4)    | 13 Oct 2020 19:50:58 |

**US3902021**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 10:17:24**

[Collection date and time \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 14 Apr 2021 06:18:15 |
| User entered empty. | System           | 13 Oct 2020 19:50:58 |

**US3902021**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 10:17:24**

[Is the participant continuing to the next visit?](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 14 Apr 2021 06:18:15 |
| User signature succeeded. | Murray Kimmel (b) (4)   | 30 Mar 2021 18:11:36 |
| User entered 'Yes (Y)'    | Taylor Atkinson (b) (4) | 07 Oct 2020 17:04:18 |



**US3902021**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 10:17:24**

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 06:18:15 |
| User entered '1'  | System           | 07 Oct 2020 17:04:18 |

US3902021

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 10:17:24

**TIMEPOINT**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| Data entry locked.   | System           | 29 Sep 2020 21:44:37 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System           | 29 Sep 2020 21:44:37 |

**US3902021**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 10:17:24**

**Was TEMPERATURE taken?**

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-09-29T17:45:07', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: 'e2b4e970-2c23-40eb-b4d8-16fe339adf00' User entered 'Yes (Y)' | System           | 29 Sep 2020 21:45:21 |
|   | System           | 29 Sep 2020 21:45:21 |

US3902021

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 10:17:24

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-09-29T17:45:10', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: 'e2b4e970-2c23-40eb-b4d8-16fe339adf00' User entered '97.3' | System           | 29 Sep 2020 21:45:21 |
|  | System           | 29 Sep 2020 21:45:21 |

US3902021

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 10:17:24

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-09-29T17:45:14', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: 'e2b4e970-2c23-40eb-b4d8-16fe339adf00' | System           | 29 Sep 2020 21:45:21 |
| User entered 'No (N)'  | System           | 29 Sep 2020 21:45:21 |

**US3902021**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 10:17:24**

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-09-29T17:45:19', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: 'e2b4e970-2c23-40eb-b4d8-16fe339adf00' | System           | 29 Sep 2020 21:45:21 |
| User entered '29 Sep 2020 17:45'   | System           | 29 Sep 2020 21:45:21 |

**US3902021**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 10:17:24**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| User entered '29 Sep 2020 17:29' | System           | 29 Sep 2020 21:44:37 |

US3902021

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 10:17:24

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| User entered '29 Sep 2020 19:59' | System           | 29 Sep 2020 21:44:37 |



US3902021

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 10:17:24

**TIMEPOINT**

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                                 | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| Data entry locked.                                | System           | 29 Sep 2020 21:44:37 |
| User entered 'Day 1, after vaccination (at home)' | System           | 29 Sep 2020 21:44:37 |

**US3902021**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 10:17:24**

**Was TEMPERATURE taken?**

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-09-29T22:17:21', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: 'a5c56cb3-c2d4-411f-be0b-57d1d94a8011' User entered 'Yes (Y)' | System           | 30 Sep 2020 02:18:59 |
|   | System           | 30 Sep 2020 02:18:59 |

US3902021

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 10:17:24

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-09-29T22:18:51', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: 'a5c56cb3-c2d4-411f-be0b-57d1d94a8011' User entered '98.6' | System           | 30 Sep 2020 02:18:59 |
|  | System           | 30 Sep 2020 02:18:59 |

US3902021

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 10:17:24

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-09-29T22:18:55', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: 'a5c56cb3-c2d4-411f-be0b-57d1d94a8011' User entered 'No (N)' | System           | 30 Sep 2020 02:18:59 |
|  | System           | 30 Sep 2020 02:18:59 |

**US3902021**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 10:17:24**

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-09-29T22:18:58', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: 'a5c56cb3-c2d4-411f-be0b-57d1d94a8011' User entered '29 Sep 2020 22:18' | System           | 30 Sep 2020 02:18:59 |
|   | System           | 30 Sep 2020 02:18:59 |

US3902021

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 10:17:24

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| User entered '29 Sep 2020 20:54' | System           | 29 Sep 2020 21:44:37 |

**US3902021**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 10:17:24**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| User entered '30 Sep 2020 11:59' | System           | 29 Sep 2020 21:44:37 |

**US3902021**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 10 Jun 2021 10:17:24**

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| Data entry locked.   | System           | 29 Sep 2020 21:44:37 |
| User entered 'Day 2' | System           | 29 Sep 2020 21:44:37 |



US3902021

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 10:17:24

Was **TEMPERATURE** taken?

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-09-30T15:26:44', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '66a8bba2-0e73-43c3-b11c-3f76a4ddb0c3' User entered 'Yes (Y)' | System           | 30 Sep 2020 19:27:26 |
|   | System           | 30 Sep 2020 19:27:26 |

US3902021

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 10:17:24

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-09-30T15:26:48', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '66a8bba2-0e73-43c3-b11c-3f76a4ddb0c3' User entered '98.8' | System           | 30 Sep 2020 19:27:26 |
|  | System           | 30 Sep 2020 19:27:26 |

US3902021

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 10:17:24

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

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-09-30T15:27:00', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '66a8bba2-0e73-43c3-b11c-3f76a4ddb0c3' User entered 'Yes (Y)' | System           | 30 Sep 2020 19:27:26 |
|   | System           | 30 Sep 2020 19:27:26 |

US3902021

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 10:17:24

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

| Audit  | User                               | Time (GMT)           |
|--|------------------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)                   | 27 Mar 2021 19:18:00 |
| 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 'Updated' (Site from System).      | (b) (4), (b) (6)                   | 08 Oct 2020 12:16:45 |
| 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). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-09-30T15:27:20', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '66a8bba2-0e73-43c3-b11c-3f76a4ddb0c3' User entered '1' | Taylor Atkinson (b) (4)<br>(b) (4) | 07 Oct 2020 17:03:24 |
| 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).   | System                             | 30 Sep 2020 19:27:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-09-30T15:27:20', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '66a8bba2-0e73-43c3-b11c-3f76a4ddb0c3' User entered '1'  | System                             | 30 Sep 2020 19:27:26 |
| User entered '1'   | System                             | 30 Sep 2020 19:27:26 |

US3902021

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 10:17:24

To **PREVENT** pain or fever from occurring

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-09-30T15:27:20', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '66a8bba2-0e73-43c3-b11c-3f76a4ddb0c3' User entered '0' | System           | 30 Sep 2020 19:27:26 |
|   | System           | 30 Sep 2020 19:27:26 |

**US3902021**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 10 Jun 2021 10:17:24**

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-09-30T15:27:24', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '66a8bba2-0e73-43c3-b11c-3f76a4ddb0c3' User entered '30 Sep 2020 15:27' | System           | 30 Sep 2020 19:27:26 |
|   | System           | 30 Sep 2020 19:27:26 |

**US3902021**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 10 Jun 2021 10:17:24**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| User entered '30 Sep 2020 12:00' | System           | 29 Sep 2020 21:44:37 |

**US3902021**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 10 Jun 2021 10:17:24**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| User entered '01 Oct 2020 11:59' | System           | 29 Sep 2020 21:44:37 |



US3902021

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 10:17:24

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| Data entry locked.   | System           | 29 Sep 2020 21:44:37 |
| User entered 'Day 3' | System           | 29 Sep 2020 21:44:37 |

US3902021

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 10:17:24

Was **TEMPERATURE** taken?

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-10-02T04:48:50', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '54ced512-7d17-4894-a4a8-a3a6971b1635' User entered 'Yes (Y)' | System           | 02 Oct 2020 08:49:02 |
|   | System           | 02 Oct 2020 08:49:02 |

US3902021

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 10:17:24

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-10-02T04:48:54', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '54ced512-7d17-4894-a4a8-a3a6971b1635' User entered '97.2' | System           | 02 Oct 2020 08:49:02 |
|  | System           | 02 Oct 2020 08:49:02 |

US3902021

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 10:17:24

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-10-02T04:48:58', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '54ced512-7d17-4894-a4a8-a3a6971b1635' | System           | 02 Oct 2020 08:49:02 |
| User entered 'No (N)'  | System           | 02 Oct 2020 08:49:02 |

**US3902021**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 10:17:24**

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-10-02T04:49:00', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '54ced512-7d17-4894-a4a8-a3a6971b1635' User entered '02 Oct 2020 04:49' | System           | 02 Oct 2020 08:49:02 |
|   | System           | 02 Oct 2020 08:49:02 |

**US3902021**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 10:17:24**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| User entered '01 Oct 2020 12:00' | System           | 29 Sep 2020 21:44:37 |

**US3902021**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 10:17:24**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| User entered '02 Oct 2020 11:59' | System           | 29 Sep 2020 21:44:37 |

US3902021

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 10:17:24

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| Data entry locked.   | System           | 29 Sep 2020 21:44:37 |
| User entered 'Day 4' | System           | 29 Sep 2020 21:44:37 |



US3902021

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 10:17:24

Was **TEMPERATURE** taken?

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-10-03T08:32:31', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: 'd535406c-f0af-4bd4-88a3-da648ac5c87d' User entered 'Yes (Y)' | System           | 03 Oct 2020 12:32:47 |
|   | System           | 03 Oct 2020 12:32:47 |

US3902021

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 10:17:24

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-10-03T08:32:33', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: 'd535406c-f0af-4bd4-88a3-da648ac5c87d' User entered '98.1' | System           | 03 Oct 2020 12:32:47 |
|  | System           | 03 Oct 2020 12:32:47 |

US3902021

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 10:17:24

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-10-03T08:32:35', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: 'd535406c-f0af-4bd4-88a3-da648ac5c87d' User entered 'No (N)' | System           | 03 Oct 2020 12:32:47 |
|  | System           | 03 Oct 2020 12:32:47 |

**US3902021**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 10 Jun 2021 10:17:24**

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-10-03T08:32:37', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: 'd535406c-f0af-4bd4-88a3-da648ac5c87d' User entered '03 Oct 2020 08:32' | System           | 03 Oct 2020 12:32:47 |
|   | System           | 03 Oct 2020 12:32:47 |

**US3902021**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 10 Jun 2021 10:17:24**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| User entered '02 Oct 2020 12:00' | System           | 29 Sep 2020 21:44:37 |

**US3902021**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 10 Jun 2021 10:17:24**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| User entered '03 Oct 2020 11:59' | System           | 29 Sep 2020 21:44:37 |

**US3902021**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 10:17:24**

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| Data entry locked.   | System           | 29 Sep 2020 21:44:37 |
| User entered 'Day 5' | System           | 29 Sep 2020 21:44:37 |

US3902021

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 10:17:24

Was **TEMPERATURE** taken?

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-10-04T08:26:06', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '6fe63dd8-ccaf-45e1-89da-9f8d46dcd84b' User entered 'Yes (Y)' | System           | 04 Oct 2020 12:26:23 |
|   | System           | 04 Oct 2020 12:26:23 |



US3902021

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 10:17:24

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-10-04T08:26:09', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '6fe63dd8-ccaf-45e1-89da-9f8d46dcd84b' User entered '97.1' | System           | 04 Oct 2020 12:26:23 |
|  | System           | 04 Oct 2020 12:26:23 |

US3902021

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 10:17:24

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-10-04T08:26:12', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '6fe63dd8-ccaf-45e1-89da-9f8d46dcd84b' User entered 'No (N)' | System           | 04 Oct 2020 12:26:23 |
|  | System           | 04 Oct 2020 12:26:23 |

**US3902021**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 10:17:24**

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-10-04T08:26:21', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '6fe63dd8-ccaf-45e1-89da-9f8d46dcd84b' User entered '04 Oct 2020 08:26' | System           | 04 Oct 2020 12:26:23 |
|   | System           | 04 Oct 2020 12:26:23 |

**US3902021**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 10:17:24**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| User entered '03 Oct 2020 12:00' | System           | 29 Sep 2020 21:44:37 |

US3902021

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 10:17:24

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| User entered '04 Oct 2020 11:59' | System           | 29 Sep 2020 21:44:37 |

US3902021

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 10:17:24

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| Data entry locked.   | System           | 29 Sep 2020 21:44:37 |
| User entered 'Day 6' | System           | 29 Sep 2020 21:44:37 |

**US3902021**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 10:17:24**

**Was TEMPERATURE taken?**

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-10-05T07:22:02', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '7bb9db55-eadb-45c5-9e04-1ebdc0ca4671' User entered 'Yes (Y)' | System           | 05 Oct 2020 11:22:14 |
|   | System           | 05 Oct 2020 11:22:14 |

US3902021

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 10:17:24

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-10-05T07:22:04', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '7bb9db55-eadb-45c5-9e04-1ebdc0ca4671' User entered '97.6' | System           | 05 Oct 2020 11:22:14 |
|  | System           | 05 Oct 2020 11:22:14 |



US3902021

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 10:17:24

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-10-05T07:22:07', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '7bb9db55-eadb-45c5-9e04-1ebdc0ca4671' User entered 'No (N)' | System           | 05 Oct 2020 11:22:14 |
|  | System           | 05 Oct 2020 11:22:14 |

**US3902021**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 10:17:24**

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-10-05T07:22:09', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '7bb9db55-eadb-45c5-9e04-1ebdc0ca4671' User entered '05 Oct 2020 07:22' | System           | 05 Oct 2020 11:22:14 |
|   | System           | 05 Oct 2020 11:22:14 |

**US3902021**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 10:17:24**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| User entered '04 Oct 2020 12:00' | System           | 29 Sep 2020 21:44:37 |

**US3902021**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 10:17:24**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| User entered '05 Oct 2020 11:59' | System           | 29 Sep 2020 21:44:37 |

**US3902021**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 10:17:24**

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| Data entry locked.   | System           | 29 Sep 2020 21:44:37 |
| User entered 'Day 7' | System           | 29 Sep 2020 21:44:37 |

**US3902021**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 10:17:24**

**Was TEMPERATURE taken?**

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-10-06T08:39:09', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '13f09881-af3a-4775-864e-6319a3865c3f' User entered 'Yes (Y)' | System           | 06 Oct 2020 12:39:35 |
|   | System           | 06 Oct 2020 12:39:35 |

US3902021

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 10:17:24

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-10-06T08:39:25', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '13f09881-af3a-4775-864e-6319a3865c3f' User entered '97.3' | System           | 06 Oct 2020 12:39:35 |
|  | System           | 06 Oct 2020 12:39:35 |

US3902021

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 10:17:24

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-10-06T08:39:28', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '13f09881-af3a-4775-864e-6319a3865c3f' User entered 'No (N)' | System           | 06 Oct 2020 12:39:35 |
|  | System           | 06 Oct 2020 12:39:35 |



**US3902021**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 10:17:24**

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-10-06T08:39:31', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '13f09881-af3a-4775-864e-6319a3865c3f' User entered '06 Oct 2020 08:39' | System           | 06 Oct 2020 12:39:35 |
|   | System           | 06 Oct 2020 12:39:35 |

**US3902021**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 10:17:24**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| User entered '05 Oct 2020 12:00' | System           | 29 Sep 2020 21:44:37 |

**US3902021**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 10:17:24**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| User entered '06 Oct 2020 11:59' | System           | 29 Sep 2020 21:44:37 |

**US3902021**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 10:17:24**

**TIMEPOINT**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| Data entry locked.   | System           | 29 Sep 2020 21:44:37 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System           | 29 Sep 2020 21:44:37 |

US3902021

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 10:17:24

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-09-29T17:45:23', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '54642794-fc68-4334-a444-5ded383b2ad1' | System           | 29 Sep 2020 21:45:48 |
| User entered 'None (1)'  | System           | 29 Sep 2020 21:45:48 |

**US3902021**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 10:17:24**

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-09-29T17:45:34', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '54642794-fc68-4334-a444-5ded383b2ad1' User entered 'No (N)' | System           | 29 Sep 2020 21:45:48 |
|  | System           | 29 Sep 2020 21:45:48 |

US3902021

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 10:17:24

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-09-29T17:45:37', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '54642794-fc68-4334-a444-5ded383b2ad1' User entered 'No (N)' | System           | 29 Sep 2020 21:45:48 |
|  | System           | 29 Sep 2020 21:45:48 |

US3902021

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 10:17:24

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-09-29T17:45:42', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '54642794-fc68-4334-a444-5ded383b2ad1' | System           | 29 Sep 2020 21:45:48 |
| User entered 'None (1)'  | System           | 29 Sep 2020 21:45:48 |



**US3902021**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 10:17:24**

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-09-29T17:45:45', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '54642794-fc68-4334-a444-5ded383b2ad1' User entered '29 Sep 2020 17:45' | System           | 29 Sep 2020 21:45:48 |
|   | System           | 29 Sep 2020 21:45:48 |

**US3902021**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 10:17:24**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| User entered '29 Sep 2020 17:29' | System           | 29 Sep 2020 21:44:37 |

**US3902021**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 10:17:24**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| User entered '29 Sep 2020 19:59' | System           | 29 Sep 2020 21:44:37 |

US3902021

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 10:17:24

**TIMEPOINT**

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                                 | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| Data entry locked.                                | System           | 29 Sep 2020 21:44:37 |
| User entered 'Day 1, after vaccination (at home)' | System           | 29 Sep 2020 21:44:37 |

US3902021

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 10:17:24

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-09-29T22:12:38', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '587f29aa-7090-4566-bac3-04e2a96ac080' | System           | 30 Sep 2020 02:16:42 |
| User entered 'Does not interfere with activity (2)'  | System           | 30 Sep 2020 02:16:42 |

**US3902021**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 10:17:24**

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

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-09-29T22:13:12', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '587f29aa-7090-4566-bac3-04e2a96ac080' User entered 'Yes (Y)' | System           | 30 Sep 2020 02:16:42 |
|   | System           | 30 Sep 2020 02:16:42 |

US3902021

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 10:17:24

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

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

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-09-29T22:16:14', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '587f29aa-7090-4566-bac3-04e2a96ac080' User entered '5' | System           | 30 Sep 2020 02:16:42 |
|   | System           | 30 Sep 2020 02:16:42 |

US3902021

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 10:17:24

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-09-29T22:16:26', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '587f29aa-7090-4566-bac3-04e2a96ac080' User entered 'No (N)' | System           | 30 Sep 2020 02:16:42 |
|  | System           | 30 Sep 2020 02:16:42 |



US3902021

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 10:17:24

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-09-29T22:16:37', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '587f29aa-7090-4566-bac3-04e2a96ac080' User entered 'None (1)' | System           | 30 Sep 2020 02:16:42 |
|  | System           | 30 Sep 2020 02:16:42 |

**US3902021**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 10:17:24**

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-09-29T22:16:40', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '587f29aa-7090-4566-bac3-04e2a96ac080' User entered '29 Sep 2020 22:16' | System           | 30 Sep 2020 02:16:42 |
|   | System           | 30 Sep 2020 02:16:42 |

**US3902021**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 10:17:24**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| User entered '29 Sep 2020 20:54' | System           | 29 Sep 2020 21:44:37 |

**US3902021**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 10:17:24**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| User entered '30 Sep 2020 11:59' | System           | 29 Sep 2020 21:44:37 |

**US3902021**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 10:17:24**

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| Data entry locked.   | System           | 29 Sep 2020 21:44:37 |
| User entered 'Day 2' | System           | 29 Sep 2020 21:44:37 |

US3902021

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 10:17:24

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-09-30T15:29:25', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: 'd700976f-d2dc-4cc6-89bf-24ea64f63744' | System           | 30 Sep 2020 19:34:08 |
| User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity (3)'   | System           | 30 Sep 2020 19:34:08 |

US3902021

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 10:17:24

Is there any REDNESS AT INJECTION SITE?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-09-30T15:29:43', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: 'd700976f-d2dc-4cc6-89bf-24ea64f63744' | System           | 30 Sep 2020 19:34:08 |
| User entered 'Yes (Y)'   | System           | 30 Sep 2020 19:34:08 |

US3902021

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 10:17:24

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

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

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-09-30T15:29:47', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: 'd700976f-d2dc-4cc6-89bf-24ea64f63744' User entered '5' | System           | 30 Sep 2020 19:34:08 |
|   | System           | 30 Sep 2020 19:34:08 |



US3902021

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 10:17:24

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-09-30T15:30:08', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: 'd700976f-d2dc-4cc6-89bf-24ea64f63744' | System           | 30 Sep 2020 19:34:08 |
| User entered 'Yes (Y)'   | System           | 30 Sep 2020 19:34:08 |

US3902021

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 10:17:24

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

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-09-30T15:32:32', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: 'd700976f-d2dc-4cc6-89bf-24ea64f63744' | System           | 30 Sep 2020 19:34:08 |
| User entered '90'  | System           | 30 Sep 2020 19:34:08 |

US3902021

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 10:17:24

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-09-30T15:34:01', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: 'd700976f-d2dc-4cc6-89bf-24ea64f63744' | System           | 30 Sep 2020 19:34:08 |
| User entered 'Does not interfere with activity (2)'  | System           | 30 Sep 2020 19:34:08 |

**US3902021**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 10:17:24**

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-09-30T15:34:05', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: 'd700976f-d2dc-4cc6-89bf-24ea64f63744' | System           | 30 Sep 2020 19:34:08 |
| User entered '30 Sep 2020 15:34'   | System           | 30 Sep 2020 19:34:08 |

**US3902021**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 10:17:24**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| User entered '30 Sep 2020 12:00' | System           | 29 Sep 2020 21:44:37 |

**US3902021**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 10:17:24**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| User entered '01 Oct 2020 11:59' | System           | 29 Sep 2020 21:44:37 |

**US3902021**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 10:17:24**

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| Data entry locked.   | System           | 29 Sep 2020 21:44:37 |
| User entered 'Day 3' | System           | 29 Sep 2020 21:44:37 |

US3902021

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 10:17:24

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-10-02T04:49:12', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: 'fe5f23dd-cb73-4476-96f7-5efc73ef8457' | System           | 02 Oct 2020 08:50:00 |
| User entered 'Does not interfere with activity (2)'  | System           | 02 Oct 2020 08:50:00 |



US3902021

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 10:17:24

Is there any REDNESS AT INJECTION SITE?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-10-02T04:49:28', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: 'fe5f23dd-cb73-4476-96f7-5efc73ef8457' | System           | 02 Oct 2020 08:50:00 |
| User entered 'No (N)'  | System           | 02 Oct 2020 08:50:00 |

US3902021

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 10:17:24

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-10-02T04:49:31', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: 'fe5f23dd-cb73-4476-96f7-5efc73ef8457' User entered 'No (N)' | System           | 02 Oct 2020 08:50:00 |
|  | System           | 02 Oct 2020 08:50:00 |

US3902021

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 10:17:24

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-10-02T04:49:43', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: 'fe5f23dd-cb73-4476-96f7-5efc73ef8457' | System           | 02 Oct 2020 08:50:00 |
| User entered 'None (1)'  | System           | 02 Oct 2020 08:50:00 |

**US3902021**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 10:17:24**

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-10-02T04:49:56', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: 'fe5f23dd-cb73-4476-96f7-5efc73ef8457' User entered '02 Oct 2020 04:49' | System           | 02 Oct 2020 08:50:00 |
|   | System           | 02 Oct 2020 08:50:00 |

**US3902021**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 10:17:24**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| User entered '01 Oct 2020 12:00' | System           | 29 Sep 2020 21:44:37 |

**US3902021**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 10:17:24**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| User entered '02 Oct 2020 11:59' | System           | 29 Sep 2020 21:44:37 |

**US3902021**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 10:17:24**

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| Data entry locked.   | System           | 29 Sep 2020 21:44:37 |
| User entered 'Day 4' | System           | 29 Sep 2020 21:44:37 |

US3902021

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 10:17:24

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-10-03T08:32:41', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: 'c0cfada9-b214-43d0-99ef-dca7a98a0cce' | System           | 03 Oct 2020 12:32:56 |
| User entered 'None (1)'  | System           | 03 Oct 2020 12:32:56 |



US3902021

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 10:17:24

Is there any REDNESS AT INJECTION SITE?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-10-03T08:32:43', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: 'c0cfada9-b214-43d0-99ef-dca7a98a0cce' User entered 'No (N)' | System           | 03 Oct 2020 12:32:56 |
|  | System           | 03 Oct 2020 12:32:56 |

US3902021

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 10:17:24

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-10-03T08:32:45', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: 'c0cfada9-b214-43d0-99ef-dca7a98a0cce' User entered 'No (N)' | System           | 03 Oct 2020 12:32:56 |
|  | System           | 03 Oct 2020 12:32:56 |

US3902021

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 10:17:24

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-10-03T08:32:52', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: 'c0cfada9-b214-43d0-99ef-dca7a98a0cce' User entered 'Does not interfere with activity (2)' | System           | 03 Oct 2020 12:32:56 |
|  | System           | 03 Oct 2020 12:32:56 |

**US3902021**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 10:17:24**

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-10-03T08:32:54', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: 'c0cfada9-b214-43d0-99ef-dca7a98a0cce' User entered '03 Oct 2020 08:32' | System           | 03 Oct 2020 12:32:56 |
|   | System           | 03 Oct 2020 12:32:56 |

**US3902021**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 10:17:24**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| User entered '02 Oct 2020 12:00' | System           | 29 Sep 2020 21:44:37 |

**US3902021**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 10:17:24**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| User entered '03 Oct 2020 11:59' | System           | 29 Sep 2020 21:44:37 |

**US3902021**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 10:17:24**

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| Data entry locked.   | System           | 29 Sep 2020 21:44:37 |
| User entered 'Day 5' | System           | 29 Sep 2020 21:44:37 |

US3902021

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 10:17:24

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-10-04T08:27:25', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '0041191c-535d-43cf-a30b-98b1e2c485df' User entered 'None (1)' | System           | 04 Oct 2020 12:27:36 |
|  | System           | 04 Oct 2020 12:27:36 |



US3902021

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 10:17:24

Is there any REDNESS AT INJECTION SITE?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-10-04T08:27:27', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '0041191c-535d-43cf-a30b-98b1e2c485df' User entered 'No (N)' | System           | 04 Oct 2020 12:27:36 |
|  | System           | 04 Oct 2020 12:27:36 |

US3902021

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 10:17:24

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-10-04T08:27:28', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '0041191c-535d-43cf-a30b-98b1e2c485df' User entered 'No (N)' | System           | 04 Oct 2020 12:27:36 |
|  | System           | 04 Oct 2020 12:27:36 |

US3902021

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 10:17:24

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-10-04T08:27:30', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '0041191c-535d-43cf-a30b-98b1e2c485df' User entered 'None (1)' | System           | 04 Oct 2020 12:27:36 |
|  | System           | 04 Oct 2020 12:27:36 |

**US3902021**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 10:17:24**

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-10-04T08:27:32', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '0041191c-535d-43cf-a30b-98b1e2c485df' User entered '04 Oct 2020 08:27' | System           | 04 Oct 2020 12:27:36 |
|   | System           | 04 Oct 2020 12:27:36 |

**US3902021**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 10:17:24**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| User entered '03 Oct 2020 12:00' | System           | 29 Sep 2020 21:44:37 |

**US3902021**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 10:17:24**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| User entered '04 Oct 2020 11:59' | System           | 29 Sep 2020 21:44:37 |

**US3902021**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 10:17:24**

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| Data entry locked.   | System           | 29 Sep 2020 21:44:37 |
| User entered 'Day 6' | System           | 29 Sep 2020 21:44:37 |

US3902021

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 10:17:24

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-10-05T07:22:12', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '18b8ccaa-d447-4e82-82db-29866773a1fd' User entered 'None (1)' | System           | 05 Oct 2020 11:22:23 |
|  | System           | 05 Oct 2020 11:22:23 |



US3902021

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 10:17:24

Is there any REDNESS AT INJECTION SITE?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-10-05T07:22:14', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '18b8ccaa-d447-4e82-82db-29866773a1fd' User entered 'No (N)' | System           | 05 Oct 2020 11:22:23 |
|  | System           | 05 Oct 2020 11:22:23 |

US3902021

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 10:17:24

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-10-05T07:22:16', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '18b8ccaa-d447-4e82-82db-29866773a1fd' User entered 'No (N)' | System           | 05 Oct 2020 11:22:23 |
|  | System           | 05 Oct 2020 11:22:23 |

US3902021

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 10:17:24

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-10-05T07:22:18', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '18b8ccaa-d447-4e82-82db-29866773a1fd' User entered 'None (1)' | System           | 05 Oct 2020 11:22:23 |
|  | System           | 05 Oct 2020 11:22:23 |

**US3902021**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 10:17:24**

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-10-05T07:22:20', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '18b8ccaa-d447-4e82-82db-29866773a1fd' User entered '05 Oct 2020 07:22' | System           | 05 Oct 2020 11:22:23 |
|   | System           | 05 Oct 2020 11:22:23 |

**US3902021**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 10:17:24**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| User entered '04 Oct 2020 12:00' | System           | 29 Sep 2020 21:44:37 |

**US3902021**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 10:17:24**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| User entered '05 Oct 2020 11:59' | System           | 29 Sep 2020 21:44:37 |

**US3902021**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 10:17:24**

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| Data entry locked.   | System           | 29 Sep 2020 21:44:37 |
| User entered 'Day 7' | System           | 29 Sep 2020 21:44:37 |

US3902021

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 10:17:24

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-10-05T21:08:39', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '8d80cdfd-8d65-4a8c-be81-5741a1fe2682' | System           | 06 Oct 2020 01:09:11 |
| User entered 'None (1)'  | System           | 06 Oct 2020 01:09:11 |



US3902021

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 10:17:24

Is there any REDNESS AT INJECTION SITE?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-10-05T21:08:46', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '8d80cdfd-8d65-4a8c-be81-5741a1fe2682' User entered 'No (N)' | System           | 06 Oct 2020 01:09:11 |
|  | System           | 06 Oct 2020 01:09:11 |

US3902021

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 10:17:24

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-10-05T21:08:49', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '8d80cdfd-8d65-4a8c-be81-5741a1fe2682' User entered 'No (N)' | System           | 06 Oct 2020 01:09:11 |
|  | System           | 06 Oct 2020 01:09:11 |

US3902021

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 10:17:24

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-10-05T21:08:54', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '8d80cdfd-8d65-4a8c-be81-5741a1fe2682' | System           | 06 Oct 2020 01:09:11 |
| User entered 'None (1)'  | System           | 06 Oct 2020 01:09:11 |

**US3902021**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 10:17:24**

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-10-05T21:09:06', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '8d80cdfd-8d65-4a8c-be81-5741a1fe2682' | System           | 06 Oct 2020 01:09:11 |
| User entered '05 Oct 2020 21:09'   | System           | 06 Oct 2020 01:09:11 |

**US3902021**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 10:17:24**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| User entered '05 Oct 2020 12:00' | System           | 29 Sep 2020 21:44:37 |

**US3902021**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 10:17:24**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| User entered '06 Oct 2020 11:59' | System           | 29 Sep 2020 21:44:37 |

**US3902021**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 10:17:24**

**TIMEPOINT**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| Data entry locked.   | System           | 29 Sep 2020 21:44:37 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System           | 29 Sep 2020 21:44:37 |

**US3902021**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 10:17:24**

**HEADACHE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-09-29T17:45:52', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: 'e637efc1-a470-4027-a4b4-f6f9f4b002f4' User entered 'None (0)' | System           | 29 Sep 2020 21:46:12 |
|  | System           | 29 Sep 2020 21:46:12 |



**US3902021**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 10:17:24**

**FATIGUE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-09-29T17:45:55', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: 'e637efc1-a470-4027-a4b4-f6f9f4b002f4' User entered 'None (0)' | System           | 29 Sep 2020 21:46:12 |
|  | System           | 29 Sep 2020 21:46:12 |

**US3902021**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 10:17:24**

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-09-29T17:45:56', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: 'e637efc1-a470-4027-a4b4-f6f9f4b002f4' User entered 'None (0)' | System           | 29 Sep 2020 21:46:12 |
|  | System           | 29 Sep 2020 21:46:12 |

**US3902021**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 10:17:24**

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-09-29T17:45:58', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: 'e637efc1-a470-4027-a4b4-f6f9f4b002f4' User entered 'None (0)' | System           | 29 Sep 2020 21:46:12 |
|  | System           | 29 Sep 2020 21:46:12 |

**US3902021**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 10:17:24**

**NAUSEA/VOMITING**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-09-29T17:46:00', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: 'e637efc1-a470-4027-a4b4-f6f9f4b002f4' User entered 'None (0)' | System           | 29 Sep 2020 21:46:12 |
|  | System           | 29 Sep 2020 21:46:12 |

**US3902021**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 10:17:24**

**CHILLS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-09-29T17:46:01', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: 'e637efc1-a470-4027-a4b4-f6f9f4b002f4' User entered 'None (0)' | System           | 29 Sep 2020 21:46:12 |
|  | System           | 29 Sep 2020 21:46:12 |

US3902021

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 10:17:24

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) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-09-29T17:46:08', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: 'e637efc1-a470-4027-a4b4-f6f9f4b002f4' User entered 'No (N)' | System           | 29 Sep 2020 21:46:12 |
|  | System           | 29 Sep 2020 21:46:12 |

**US3902021**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 10:17:24**

[PC Time stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-09-29T17:46:11', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: 'e637efc1-a470-4027-a4b4-f6f9f4b002f4' User entered '29 Sep 2020 17:46' | System           | 29 Sep 2020 21:46:12 |
|   | System           | 29 Sep 2020 21:46:12 |

**US3902021**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 10:17:24**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| User entered '29 Sep 2020 17:29' | System           | 29 Sep 2020 21:44:37 |



**US3902021**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 10:17:24**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| User entered '29 Sep 2020 19:59' | System           | 29 Sep 2020 21:44:37 |

US3902021

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 10:17:24

**TIMEPOINT**

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                                 | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| Data entry locked.                                | System           | 29 Sep 2020 21:44:37 |
| User entered 'Day 1, after vaccination (at home)' | System           | 29 Sep 2020 21:44:37 |

**US3902021**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 10:17:24**

**HEADACHE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-09-29T22:16:45', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '80554e7f-6a7a-4363-ac20-8b6b5a46286e' User entered 'None (0)' | System           | 30 Sep 2020 02:17:04 |
|  | System           | 30 Sep 2020 02:17:04 |

**US3902021**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 10:17:24**

**FATIGUE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-09-29T22:16:47', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '80554e7f-6a7a-4363-ac20-8b6b5a46286e' User entered 'None (0)' | System           | 30 Sep 2020 02:17:04 |
|  | System           | 30 Sep 2020 02:17:04 |

**US3902021**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 10:17:24**

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-09-29T22:16:49', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '80554e7f-6a7a-4363-ac20-8b6b5a46286e' User entered 'None (0)' | System           | 30 Sep 2020 02:17:04 |
|  | System           | 30 Sep 2020 02:17:04 |

**US3902021**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 10:17:24**

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-09-29T22:16:52', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '80554e7f-6a7a-4363-ac20-8b6b5a46286e' User entered 'None (0)' | System           | 30 Sep 2020 02:17:04 |
|  | System           | 30 Sep 2020 02:17:04 |

**US3902021**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 10:17:24**

**NAUSEA/VOMITING**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-09-29T22:16:54', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '80554e7f-6a7a-4363-ac20-8b6b5a46286e' User entered 'None (0)' | System           | 30 Sep 2020 02:17:04 |
|  | System           | 30 Sep 2020 02:17:04 |

**US3902021**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 10:17:24**

**CHILLS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-09-29T22:16:56', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '80554e7f-6a7a-4363-ac20-8b6b5a46286e' User entered 'None (0)' | System           | 30 Sep 2020 02:17:04 |
|  | System           | 30 Sep 2020 02:17:04 |



US3902021

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 10:17:24

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) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-09-29T22:16:58', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '80554e7f-6a7a-4363-ac20-8b6b5a46286e' User entered 'No (N)' | System           | 30 Sep 2020 02:17:04 |
|  | System           | 30 Sep 2020 02:17:04 |

**US3902021**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 10:17:24**

[PC Time stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-09-29T22:17:00', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '80554e7f-6a7a-4363-ac20-8b6b5a46286e' User entered '29 Sep 2020 22:17' | System           | 30 Sep 2020 02:17:04 |
|   | System           | 30 Sep 2020 02:17:04 |

**US3902021**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 10:17:24**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| User entered '29 Sep 2020 20:54' | System           | 29 Sep 2020 21:44:37 |

**US3902021**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 10:17:24**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| User entered '30 Sep 2020 11:59' | System           | 29 Sep 2020 21:44:37 |

**US3902021**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 10:17:24**

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| Data entry locked.   | System           | 29 Sep 2020 21:44:37 |
| User entered 'Day 2' | System           | 29 Sep 2020 21:44:37 |

**US3902021**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 10:17:24**

**HEADACHE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-09-30T15:34:12', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '40509342-906e-4db1-86ec-10e160705016' | System           | 30 Sep 2020 19:35:51 |
| User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'  | System           | 30 Sep 2020 19:35:51 |

**US3902021**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 10:17:24**

**FATIGUE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-09-30T15:34:17', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '40509342-906e-4db1-86ec-10e160705016' | System           | 30 Sep 2020 19:35:51 |
| User entered 'Significant; prevents daily activity (3)'  | System           | 30 Sep 2020 19:35:51 |

**US3902021**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 10:17:24**

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-09-30T15:34:27', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '40509342-906e-4db1-86ec-10e160705016' | System           | 30 Sep 2020 19:35:51 |
| User entered 'Significant; prevents daily activity (3)'  | System           | 30 Sep 2020 19:35:51 |



**US3902021**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 10:17:24**

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-09-30T15:34:42', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '40509342-906e-4db1-86ec-10e160705016' | System           | 30 Sep 2020 19:35:51 |
| User entered 'No interference with activity (1)'   | System           | 30 Sep 2020 19:35:51 |

**US3902021**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 10:17:24**

**NAUSEA/VOMITING**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-09-30T15:34:45', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '40509342-906e-4db1-86ec-10e160705016' User entered 'None (0)' | System           | 30 Sep 2020 19:35:51 |
|  | System           | 30 Sep 2020 19:35:51 |

**US3902021**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 10:17:24**

**CHILLS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-09-30T15:35:39', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '40509342-906e-4db1-86ec-10e160705016' User entered 'None (0)' | System           | 30 Sep 2020 19:35:51 |
|  | System           | 30 Sep 2020 19:35:51 |

US3902021

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 10:17:24

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) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-09-30T15:35:45', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '40509342-906e-4db1-86ec-10e160705016' User entered 'No (N)' | System           | 30 Sep 2020 19:35:51 |
|  | System           | 30 Sep 2020 19:35:51 |

**US3902021**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 10:17:24**

[PC Time stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-09-30T15:35:48', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '40509342-906e-4db1-86ec-10e160705016' User entered '30 Sep 2020 15:35' | System           | 30 Sep 2020 19:35:51 |
|   | System           | 30 Sep 2020 19:35:51 |

**US3902021**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 10:17:24**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| User entered '30 Sep 2020 12:00' | System           | 29 Sep 2020 21:44:37 |

**US3902021**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 10:17:24**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| User entered '01 Oct 2020 11:59' | System           | 29 Sep 2020 21:44:37 |

**US3902021**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 10:17:24**

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| Data entry locked.   | System           | 29 Sep 2020 21:44:37 |
| User entered 'Day 3' | System           | 29 Sep 2020 21:44:37 |



**US3902021**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 10:17:24**

**HEADACHE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-10-02T04:50:04', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '0b0f09fe-ed97-4612-bc03-88e7b839465b' | System           | 02 Oct 2020 08:50:46 |
| User entered 'No interference with activity (1)'   | System           | 02 Oct 2020 08:50:46 |

**US3902021**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 10:17:24**

**FATIGUE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-10-02T04:50:06', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '0b0f09fe-ed97-4612-bc03-88e7b839465b' User entered 'None (0)' | System           | 02 Oct 2020 08:50:46 |
|  | System           | 02 Oct 2020 08:50:46 |

**US3902021**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 10:17:24**

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-10-02T04:50:09', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '0b0f09fe-ed97-4612-bc03-88e7b839465b' User entered 'None (0)' | System           | 02 Oct 2020 08:50:46 |
|  | System           | 02 Oct 2020 08:50:46 |

**US3902021**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 10:17:24**

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-10-02T04:50:15', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '0b0f09fe-ed97-4612-bc03-88e7b839465b' User entered 'None (0)' | System           | 02 Oct 2020 08:50:46 |
|  | System           | 02 Oct 2020 08:50:46 |

**US3902021**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 10:17:24**

**NAUSEA/VOMITING**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-10-02T04:50:20', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '0b0f09fe-ed97-4612-bc03-88e7b839465b' User entered 'None (0)' | System           | 02 Oct 2020 08:50:46 |
|  | System           | 02 Oct 2020 08:50:46 |

**US3902021**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 10:17:24**

**CHILLS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-10-02T04:50:22', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '0b0f09fe-ed97-4612-bc03-88e7b839465b' User entered 'None (0)' | System           | 02 Oct 2020 08:50:46 |
|  | System           | 02 Oct 2020 08:50:46 |

US3902021

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 10:17:24

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) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-10-02T04:50:28', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '0b0f09fe-ed97-4612-bc03-88e7b839465b' User entered 'No (N)' | System           | 02 Oct 2020 08:50:46 |
|  | System           | 02 Oct 2020 08:50:46 |

**US3902021**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 10:17:24**

[PC Time stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-10-02T04:50:45', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '0b0f09fe-ed97-4612-bc03-88e7b839465b' User entered '02 Oct 2020 04:50' | System           | 02 Oct 2020 08:50:46 |
|   | System           | 02 Oct 2020 08:50:46 |



**US3902021**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 10:17:24**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| User entered '01 Oct 2020 12:00' | System           | 29 Sep 2020 21:44:37 |

**US3902021**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 10:17:24**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| User entered '02 Oct 2020 11:59' | System           | 29 Sep 2020 21:44:37 |

**US3902021**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 10:17:24**

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| Data entry locked.   | System           | 29 Sep 2020 21:44:37 |
| User entered 'Day 4' | System           | 29 Sep 2020 21:44:37 |

**US3902021**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 10:17:24**

**HEADACHE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-10-03T08:32:57', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: 'd20531c9-61ec-40da-ba3d-38440923db28' User entered 'None (0)' | System           | 04 Oct 2020 12:24:36 |
|  | System           | 04 Oct 2020 12:24:36 |

**US3902021**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 10:17:24**

**FATIGUE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-10-03T08:32:59', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: 'd20531c9-61ec-40da-ba3d-38440923db28' User entered 'None (0)' | System           | 04 Oct 2020 12:24:36 |
|  | System           | 04 Oct 2020 12:24:36 |

**US3902021**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 10:17:24**

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-10-03T08:33:01', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: 'd20531c9-61ec-40da-ba3d-38440923db28' User entered 'None (0)' | System           | 04 Oct 2020 12:24:36 |
|  | System           | 04 Oct 2020 12:24:36 |

**US3902021**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 10:17:24**

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-10-03T08:33:08', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: 'd20531c9-61ec-40da-ba3d-38440923db28' User entered 'None (0)' | System           | 04 Oct 2020 12:24:36 |
|  | System           | 04 Oct 2020 12:24:36 |

**US3902021**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 10:17:24**

**NAUSEA/VOMITING**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-10-03T08:33:09', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: 'd20531c9-61ec-40da-ba3d-38440923db28' User entered 'None (0)' | System           | 04 Oct 2020 12:24:36 |
|  | System           | 04 Oct 2020 12:24:36 |



**US3902021**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 10:17:24**

**CHILLS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-10-03T08:33:10', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: 'd20531c9-61ec-40da-ba3d-38440923db28' User entered 'None (0)' | System           | 04 Oct 2020 12:24:36 |
|  | System           | 04 Oct 2020 12:24:36 |

US3902021

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 10:17:24

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) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-10-03T08:33:12', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: 'd20531c9-61ec-40da-ba3d-38440923db28' User entered 'No (N)' | System           | 04 Oct 2020 12:24:36 |
|  | System           | 04 Oct 2020 12:24:36 |

**US3902021**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 10:17:24**

[PC Time stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-10-03T08:33:21', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: 'd20531c9-61ec-40da-ba3d-38440923db28' User entered '03 Oct 2020 08:33' | System           | 04 Oct 2020 12:24:36 |
|   | System           | 04 Oct 2020 12:24:36 |

**US3902021**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 10:17:24**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| User entered '02 Oct 2020 12:00' | System           | 29 Sep 2020 21:44:37 |

**US3902021**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 10:17:24**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| User entered '03 Oct 2020 11:59' | System           | 29 Sep 2020 21:44:37 |

**US3902021**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 10:17:24**

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| Data entry locked.   | System           | 29 Sep 2020 21:44:37 |
| User entered 'Day 5' | System           | 29 Sep 2020 21:44:37 |

**US3902021**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 10:17:24**

**HEADACHE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-10-04T08:27:34', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '710dba02-764c-4171-8bef-0c278b2e9eb0' User entered 'None (0)' | System           | 04 Oct 2020 12:27:48 |
|  | System           | 04 Oct 2020 12:27:48 |

**US3902021**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 10:17:24**

**FATIGUE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-10-04T08:27:36', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '710dba02-764c-4171-8bef-0c278b2e9eb0' User entered 'None (0)' | System           | 04 Oct 2020 12:27:48 |
|  | System           | 04 Oct 2020 12:27:48 |



**US3902021**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 10:17:24**

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-10-04T08:27:37', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '710dba02-764c-4171-8bef-0c278b2e9eb0' User entered 'None (0)' | System           | 04 Oct 2020 12:27:48 |
|  | System           | 04 Oct 2020 12:27:48 |

**US3902021**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 10:17:24**

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-10-04T08:27:38', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '710dba02-764c-4171-8bef-0c278b2e9eb0' User entered 'None (0)' | System           | 04 Oct 2020 12:27:48 |
|  | System           | 04 Oct 2020 12:27:48 |

**US3902021**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 10:17:24**

**NAUSEA/VOMITING**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-10-04T08:27:40', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '710dba02-764c-4171-8bef-0c278b2e9eb0' User entered 'None (0)' | System           | 04 Oct 2020 12:27:48 |
|  | System           | 04 Oct 2020 12:27:48 |

**US3902021**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 10:17:24**

**CHILLS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-10-04T08:27:42', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '710dba02-764c-4171-8bef-0c278b2e9eb0' User entered 'None (0)' | System           | 04 Oct 2020 12:27:48 |
|  | System           | 04 Oct 2020 12:27:48 |

US3902021

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 10:17:24

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) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-10-04T08:27:45', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '710dba02-764c-4171-8bef-0c278b2e9eb0' User entered 'No (N)' | System           | 04 Oct 2020 12:27:48 |
|  | System           | 04 Oct 2020 12:27:48 |

**US3902021**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 10:17:24**

[PC Time stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-10-04T08:27:46', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '710dba02-764c-4171-8bef-0c278b2e9eb0' User entered '04 Oct 2020 08:27' | System           | 04 Oct 2020 12:27:48 |
|   | System           | 04 Oct 2020 12:27:48 |

**US3902021**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 10:17:24**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| User entered '03 Oct 2020 12:00' | System           | 29 Sep 2020 21:44:37 |

**US3902021**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 10:17:24**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| User entered '04 Oct 2020 11:59' | System           | 29 Sep 2020 21:44:37 |



**US3902021**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 10:17:24**

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| Data entry locked.   | System           | 29 Sep 2020 21:44:37 |
| User entered 'Day 6' | System           | 29 Sep 2020 21:44:37 |

**US3902021**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 10:17:24**

**HEADACHE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-10-05T07:22:22', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '31e96b80-db50-4e44-9ba9-f9ce2b7fce71' User entered 'None (0)' | System           | 05 Oct 2020 11:22:36 |
|  | System           | 05 Oct 2020 11:22:36 |

**US3902021**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 10:17:24**

**FATIGUE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-10-05T07:22:24', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '31e96b80-db50-4e44-9ba9-f9ce2b7fce71' User entered 'None (0)' | System           | 05 Oct 2020 11:22:36 |
|  | System           | 05 Oct 2020 11:22:36 |

**US3902021**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 10:17:24**

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-10-05T07:22:25', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '31e96b80-db50-4e44-9ba9-f9ce2b7fce71' User entered 'None (0)' | System           | 05 Oct 2020 11:22:36 |
|  | System           | 05 Oct 2020 11:22:36 |

US3902021

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 10:17:24

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-10-05T07:22:26', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '31e96b80-db50-4e44-9ba9-f9ce2b7fce71' User entered 'None (0)' | System           | 05 Oct 2020 11:22:36 |
|  | System           | 05 Oct 2020 11:22:36 |

**US3902021**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 10:17:24**

**NAUSEA/VOMITING**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-10-05T07:22:27', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '31e96b80-db50-4e44-9ba9-f9ce2b7fce71' User entered 'None (0)' | System           | 05 Oct 2020 11:22:36 |
|  | System           | 05 Oct 2020 11:22:36 |

**US3902021**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 10:17:24**

**CHILLS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-10-05T07:22:28', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '31e96b80-db50-4e44-9ba9-f9ce2b7fce71' User entered 'None (0)' | System           | 05 Oct 2020 11:22:36 |
|  | System           | 05 Oct 2020 11:22:36 |

US3902021

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 10:17:24

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) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-10-05T07:22:30', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '31e96b80-db50-4e44-9ba9-f9ce2b7fce71' User entered 'No (N)' | System           | 05 Oct 2020 11:22:36 |
|  | System           | 05 Oct 2020 11:22:36 |



**US3902021**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 10:17:24**

[PC Time stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-10-05T07:22:31', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '31e96b80-db50-4e44-9ba9-f9ce2b7fce71' User entered '05 Oct 2020 07:22' | System           | 05 Oct 2020 11:22:36 |
|   | System           | 05 Oct 2020 11:22:36 |

**US3902021**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 10:17:24**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| User entered '04 Oct 2020 12:00' | System           | 29 Sep 2020 21:44:37 |

**US3902021**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 10:17:24**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| User entered '05 Oct 2020 11:59' | System           | 29 Sep 2020 21:44:37 |

**US3902021**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 10:17:24**

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| Data entry locked.   | System           | 29 Sep 2020 21:44:37 |
| User entered 'Day 7' | System           | 29 Sep 2020 21:44:37 |

US3902021

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 10:17:24

**HEADACHE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-10-05T21:09:13', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: 'd3d4cf0c-1bc1-4a46-a945-7c37005eeb95' | System           | 06 Oct 2020 01:09:29 |
| User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'  | System           | 06 Oct 2020 01:09:29 |

**US3902021**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 10:17:24**

**FATIGUE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-10-05T21:09:15', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: 'd3d4cf0c-1bc1-4a46-a945-7c37005eeb95' User entered 'None (0)' | System           | 06 Oct 2020 01:09:29 |
|  | System           | 06 Oct 2020 01:09:29 |

**US3902021**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 10:17:24**

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-10-05T21:09:17', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: 'd3d4cf0c-1bc1-4a46-a945-7c37005eeb95' User entered 'None (0)' | System           | 06 Oct 2020 01:09:29 |
|  | System           | 06 Oct 2020 01:09:29 |

US3902021

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 10:17:24

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-10-05T21:09:18', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: 'd3d4cf0c-1bc1-4a46-a945-7c37005eeb95' User entered 'None (0)' | System           | 06 Oct 2020 01:09:29 |
|  | System           | 06 Oct 2020 01:09:29 |



**US3902021**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 10:17:24**

**NAUSEA/VOMITING**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-10-05T21:09:21', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: 'd3d4cf0c-1bc1-4a46-a945-7c37005eeb95' User entered 'None (0)' | System           | 06 Oct 2020 01:09:29 |
|  | System           | 06 Oct 2020 01:09:29 |

**US3902021**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 10:17:24**

**CHILLS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-10-05T21:09:22', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: 'd3d4cf0c-1bc1-4a46-a945-7c37005eeb95' User entered 'None (0)' | System           | 06 Oct 2020 01:09:29 |
|  | System           | 06 Oct 2020 01:09:29 |

US3902021

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 10:17:24

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) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-10-05T21:09:25', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: 'd3d4cf0c-1bc1-4a46-a945-7c37005eeb95' User entered 'No (N)' | System           | 06 Oct 2020 01:09:29 |
|  | System           | 06 Oct 2020 01:09:29 |

**US3902021**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 10:17:24**

[PC Time stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-10-05T21:09:27', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: 'd3d4cf0c-1bc1-4a46-a945-7c37005eeb95' User entered '05 Oct 2020 21:09' | System           | 06 Oct 2020 01:09:29 |
|   | System           | 06 Oct 2020 01:09:29 |

**US3902021**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 10:17:24**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| User entered '05 Oct 2020 12:00' | System           | 29 Sep 2020 21:44:37 |

**US3902021**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 10:17:24**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| User entered '06 Oct 2020 11:59' | System           | 29 Sep 2020 21:44:37 |

**US3902021**

**Folder: Diary Dose 2 (1)**

**Form: Headache\_Day(8)**

**Generated On: 10 Jun 2021 10:17:24**

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| Data entry locked.   | System           | 06 Oct 2020 01:09:29 |
| User entered 'Day 8' | System           | 06 Oct 2020 01:09:29 |

US3902021

Folder: Diary Dose 2 (1)

Form: Headache\_Day(8)

Generated On: 10 Jun 2021 10:17:24

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

| Audit   | User               | Time (GMT)           |
|---|--------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)   | 27 Mar 2021 19:18:00 |
| User closed query 'Per DM CLR: Please note, Per Diary Dose 2 Record, symptom of HEADACHE persist beyond Day 7 (start date: Day 8; end date: Day 11). Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification.<br>' (Site from DM).  | (b) (4), (b) (6)   | 22 Feb 2021 05:27:03 |
| Query 'Per DM CLR: Please note, Per Diary Dose 2 Record, symptom of HEADACHE persist beyond Day 7 (start date: Day 8; end date: Day 11). Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification.<br>' answered with 'solicited AE does not meet AE reporting criteria' (Site from DM). | Bram Swarr (b) (4) | 19 Feb 2021 21:40:04 |
| User opened query 'Per DM CLR: Please note, Per Diary Dose 2 Record, symptom of HEADACHE persist beyond Day 7 (start date: Day 8; end date: Day 11). Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification.<br>' (Site from DM).  | (b) (4), (b) (6)   | 12 Feb 2021 03:17:58 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-10-07T09:35:24', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: 'fce80c42-6343-4f84-8744-fd6db34fd1c0'  | System             | 07 Oct 2020 13:35:34 |
| User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'   | System             | 07 Oct 2020 13:35:34 |



**US3902021**

**Folder: Diary Dose 2 (1)**

**Form: Headache\_Day(8)**

**Generated On: 10 Jun 2021 10:17:24**

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-10-07T09:35:29', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: 'fce80c42-6343-4f84-8744-fd6db34fd1c0' User entered '07 Oct 2020 09:35' | System           | 07 Oct 2020 13:35:34 |
|   | System           | 07 Oct 2020 13:35:34 |

**US3902021**

**Folder: Diary Dose 2 (1)**

**Form: Headache\_Day(8)**

**Generated On: 10 Jun 2021 10:17:24**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| User entered '06 Oct 2020 12:00' | System           | 06 Oct 2020 01:09:29 |

**US3902021**

**Folder: Diary Dose 2 (1)**

**Form: Headache\_Day(8)**

**Generated On: 10 Jun 2021 10:17:24**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| User entered '07 Oct 2020 11:59' | System           | 06 Oct 2020 01:09:29 |

**US3902021**

**Folder: Diary Dose 2 (1)**

**Form: Headache\_Day(9)**

**Generated On: 10 Jun 2021 10:17:24**

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| Data entry locked.   | System           | 06 Oct 2020 01:09:29 |
| User entered 'Day 9' | System           | 06 Oct 2020 01:09:29 |

**US3902021**

**Folder: Diary Dose 2 (1)**

**Form: Headache\_Day(9)**

**Generated On: 10 Jun 2021 10:17:24**

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-10-08T00:47:19', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: 'c4101bf1-1f7e-4598-a0c8-d4999ba10f0a' | System           | 08 Oct 2020 04:47:25 |
| User entered 'No interference with activity (1)'   | System           | 08 Oct 2020 04:47:25 |

**US3902021**

**Folder: Diary Dose 2 (1)**

**Form: Headache\_Day(9)**

**Generated On: 10 Jun 2021 10:17:24**

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-10-08T00:47:22', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: 'c4101bf1-1f7e-4598-a0c8-d4999ba10f0a' User entered '08 Oct 2020 00:47' | System           | 08 Oct 2020 04:47:25 |
|   | System           | 08 Oct 2020 04:47:25 |

**US3902021**

**Folder: Diary Dose 2 (1)**

**Form: Headache\_Day(9)**

**Generated On: 10 Jun 2021 10:17:24**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| User entered '07 Oct 2020 12:00' | System           | 06 Oct 2020 01:09:29 |

**US3902021**

**Folder: Diary Dose 2 (1)**

**Form: Headache\_Day(9)**

**Generated On: 10 Jun 2021 10:17:24**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| User entered '08 Oct 2020 11:59' | System           | 06 Oct 2020 01:09:29 |



**US3902021**

**Folder: Diary Dose 2 (1)**

**Form: Headache\_Day(10)**

**Generated On: 10 Jun 2021 10:17:24**

**TIMEPOINT**

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| Data hard locked.     | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| Data entry locked.    | System           | 07 Oct 2020 13:35:34 |
| User entered 'Day 10' | System           | 07 Oct 2020 13:35:34 |

**US3902021**

**Folder: Diary Dose 2 (1)**

**Form: Headache\_Day(10)**

**Generated On: 10 Jun 2021 10:17:24**

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-10-08T23:02:54', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: 'd62488a1-8dde-4896-b8ea-4e024af614cb' | System           | 09 Oct 2020 03:02:59 |
| User entered 'No interference with activity (1)'   | System           | 09 Oct 2020 03:02:59 |

**US3902021**

**Folder: Diary Dose 2 (1)**

**Form: Headache\_Day(10)**

**Generated On: 10 Jun 2021 10:17:24**

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-10-08T23:02:57', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: 'd62488a1-8dde-4896-b8ea-4e024af614cb' User entered '08 Oct 2020 23:02' | System           | 09 Oct 2020 03:02:59 |
|   | System           | 09 Oct 2020 03:02:59 |

**US3902021**

**Folder: Diary Dose 2 (1)**

**Form: Headache\_Day(10)**

**Generated On: 10 Jun 2021 10:17:24**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| User entered '08 Oct 2020 12:00' | System           | 07 Oct 2020 13:35:34 |

**US3902021**

**Folder: Diary Dose 2 (1)**

**Form: Headache\_Day(10)**

**Generated On: 10 Jun 2021 10:17:24**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| User entered '09 Oct 2020 11:59' | System           | 07 Oct 2020 13:35:34 |

**US3902021**

**Folder: Diary Dose 2 (1)**

**Form: Headache\_Day(11)**

**Generated On: 10 Jun 2021 10:17:24**

**TIMEPOINT**

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| Data hard locked.     | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| Data entry locked.    | System           | 08 Oct 2020 04:47:25 |
| User entered 'Day 11' | System           | 08 Oct 2020 04:47:25 |

**US3902021**

**Folder: Diary Dose 2 (1)**

**Form: Headache\_Day(11)**

**Generated On: 10 Jun 2021 10:17:24**

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

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-10-10T07:25:09', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '1592083b-ae82-4ce4-bdad-cc8ff655990f' User entered 'No interference with activity (1)' | System           | 10 Oct 2020 11:25:14 |
|   | System           | 10 Oct 2020 11:25:14 |

**US3902021**

**Folder: Diary Dose 2 (1)**

**Form: Headache\_Day(11)**

**Generated On: 10 Jun 2021 10:17:24**

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-10-10T07:25:11', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '1592083b-ae82-4ce4-bdad-cc8ff655990f' User entered '10 Oct 2020 07:25' | System           | 10 Oct 2020 11:25:14 |
|   | System           | 10 Oct 2020 11:25:14 |



**US3902021**

**Folder: Diary Dose 2 (1)**

**Form: Headache\_Day(11)**

**Generated On: 10 Jun 2021 10:17:24**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| User entered '09 Oct 2020 12:00' | System           | 08 Oct 2020 04:47:25 |

**US3902021**

**Folder: Diary Dose 2 (1)**

**Form: Headache\_Day(11)**

**Generated On: 10 Jun 2021 10:17:24**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| User entered '10 Oct 2020 11:59' | System           | 08 Oct 2020 04:47:25 |

**US3902021**

**Folder: Diary Dose 2 (1)**

**Form: Headache\_Day(12)**

**Generated On: 10 Jun 2021 10:17:24**

**TIMEPOINT**

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| Data hard locked.     | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| Data entry locked.    | System           | 09 Oct 2020 03:02:59 |
| User entered 'Day 12' | System           | 09 Oct 2020 03:02:59 |

**US3902021**

**Folder: Diary Dose 2 (1)**

**Form: Headache\_Day(12)**

**Generated On: 10 Jun 2021 10:17:24**

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-10-11T08:12:55', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: 'c76d1dd2-4cd8-4c5d-949d-748b95abc9b9' User entered 'None (0)' | System           | 11 Oct 2020 12:13:01 |
|  | System           | 11 Oct 2020 12:13:01 |

**US3902021**

**Folder: Diary Dose 2 (1)**

**Form: Headache\_Day(12)**

**Generated On: 10 Jun 2021 10:17:24**

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-10-11T08:12:59', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: 'c76d1dd2-4cd8-4c5d-949d-748b95abc9b9' User entered '11 Oct 2020 08:12' | System           | 11 Oct 2020 12:13:01 |
|   | System           | 11 Oct 2020 12:13:01 |

**US3902021**

**Folder: Diary Dose 2 (1)**

**Form: Headache\_Day(12)**

**Generated On: 10 Jun 2021 10:17:24**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| User entered '10 Oct 2020 12:00' | System           | 09 Oct 2020 03:02:59 |

**US3902021**

**Folder: Diary Dose 2 (1)**

**Form: Headache\_Day(12)**

**Generated On: 10 Jun 2021 10:17:24**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| User entered '11 Oct 2020 11:59' | System           | 09 Oct 2020 03:02:59 |

**US3902021**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(8)**

**Generated On: 10 Jun 2021 10:17:24**

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| Data entry locked.   | System           | 06 Oct 2020 01:09:29 |
| User entered 'Day 8' | System           | 06 Oct 2020 01:09:29 |



US3902021

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(8)

Generated On: 10 Jun 2021 10:17:24

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) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-10-07T09:35:33', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: 'aa7040fb-4ec2-4c4c-8d9f-bdfcf50fc022' | System           | 07 Oct 2020 13:35:37 |
| User entered 'No (N)'  | System           | 07 Oct 2020 13:35:37 |

**US3902021**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(8)**

**Generated On: 10 Jun 2021 10:17:24**

[PC Time stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-10-07T09:35:35', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: 'aa7040fb-4ec2-4c4c-8d9f-bdfcf50fc022' | System           | 07 Oct 2020 13:35:37 |
| User entered '07 Oct 2020 09:35'   | System           | 07 Oct 2020 13:35:37 |

**US3902021**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(8)**

**Generated On: 10 Jun 2021 10:17:24**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| User entered '06 Oct 2020 12:00' | System           | 06 Oct 2020 01:09:29 |

**US3902021**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(8)**

**Generated On: 10 Jun 2021 10:17:24**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| User entered '07 Oct 2020 11:59' | System           | 06 Oct 2020 01:09:29 |

**US3902021**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(9)**

**Generated On: 10 Jun 2021 10:17:24**

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| Data entry locked.   | System           | 06 Oct 2020 01:09:29 |
| User entered 'Day 9' | System           | 06 Oct 2020 01:09:29 |

US3902021

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(9)

Generated On: 10 Jun 2021 10:17:24

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) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-10-08T00:47:27', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '39006d3d-232f-4913-810b-0e8a028bf460' User entered 'No (N)' | System           | 08 Oct 2020 04:47:33 |
|  | System           | 08 Oct 2020 04:47:33 |

**US3902021**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(9)**

**Generated On: 10 Jun 2021 10:17:24**

[PC Time stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-10-08T00:47:29', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '39006d3d-232f-4913-810b-0e8a028bf460' User entered '08 Oct 2020 00:47' | System           | 08 Oct 2020 04:47:33 |
|   | System           | 08 Oct 2020 04:47:33 |

**US3902021**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(9)**

**Generated On: 10 Jun 2021 10:17:24**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| User entered '07 Oct 2020 12:00' | System           | 06 Oct 2020 01:09:29 |



**US3902021**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(9)**

**Generated On: 10 Jun 2021 10:17:24**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| User entered '08 Oct 2020 11:59' | System           | 06 Oct 2020 01:09:29 |

**US3902021**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(10)**

**Generated On: 10 Jun 2021 10:17:24**

**TIMEPOINT**

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| Data hard locked.     | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| Data entry locked.    | System           | 07 Oct 2020 13:35:34 |
| User entered 'Day 10' | System           | 07 Oct 2020 13:35:34 |

US3902021

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(10)

Generated On: 10 Jun 2021 10:17:24

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) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-10-08T23:03:01', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '9f2631ee-bf2e-4033-ba5e-17f9a670c7a4' User entered 'No (N)' | System           | 09 Oct 2020 03:03:08 |
|  | System           | 09 Oct 2020 03:03:08 |

**US3902021**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(10)**

**Generated On: 10 Jun 2021 10:17:24**

[PC Time stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-10-08T23:03:03', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '9f2631ee-bf2e-4033-ba5e-17f9a670c7a4' User entered '08 Oct 2020 23:03' | System           | 09 Oct 2020 03:03:08 |
|   | System           | 09 Oct 2020 03:03:08 |

**US3902021**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(10)**

**Generated On: 10 Jun 2021 10:17:24**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| User entered '08 Oct 2020 12:00' | System           | 07 Oct 2020 13:35:34 |

**US3902021**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(10)**

**Generated On: 10 Jun 2021 10:17:24**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| User entered '09 Oct 2020 11:59' | System           | 07 Oct 2020 13:35:34 |

**US3902021**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(11)**

**Generated On: 10 Jun 2021 10:17:24**

**TIMEPOINT**

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| Data hard locked.     | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| Data entry locked.    | System           | 08 Oct 2020 04:47:25 |
| User entered 'Day 11' | System           | 08 Oct 2020 04:47:25 |

US3902021

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(11)

Generated On: 10 Jun 2021 10:17:24

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) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-10-10T07:25:17', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '4328a64e-657f-4cfb-9ca6-33e3f3511274' User entered 'No (N)' | System           | 10 Oct 2020 11:25:21 |
|  | System           | 10 Oct 2020 11:25:21 |



**US3902021**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(11)**

**Generated On: 10 Jun 2021 10:17:24**

[PC Time stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-10-10T07:25:19', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '4328a64e-657f-4cfb-9ca6-33e3f3511274' User entered '10 Oct 2020 07:25' | System           | 10 Oct 2020 11:25:21 |
|   | System           | 10 Oct 2020 11:25:21 |

**US3902021**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(11)**

**Generated On: 10 Jun 2021 10:17:24**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| User entered '09 Oct 2020 12:00' | System           | 08 Oct 2020 04:47:25 |

**US3902021**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(11)**

**Generated On: 10 Jun 2021 10:17:24**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| User entered '10 Oct 2020 11:59' | System           | 08 Oct 2020 04:47:25 |

**US3902021**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(12)**

**Generated On: 10 Jun 2021 10:17:24**

**TIMEPOINT**

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| Data hard locked.     | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| Data entry locked.    | System           | 09 Oct 2020 03:02:59 |
| User entered 'Day 12' | System           | 09 Oct 2020 03:02:59 |

US3902021

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(12)

Generated On: 10 Jun 2021 10:17:24

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) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-10-11T08:13:02', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '946afcb0-4e26-445e-8af5-ee3c014c3b0f' User entered 'No (N)' | System           | 11 Oct 2020 12:13:05 |
|  | System           | 11 Oct 2020 12:13:05 |

**US3902021**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(12)**

**Generated On: 10 Jun 2021 10:17:24**

[PC Time stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-10-11T08:13:04', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '946afcb0-4e26-445e-8af5-ee3c014c3b0f' User entered '11 Oct 2020 08:13' | System           | 11 Oct 2020 12:13:05 |
|   | System           | 11 Oct 2020 12:13:05 |

**US3902021**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(12)**

**Generated On: 10 Jun 2021 10:17:24**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| User entered '10 Oct 2020 12:00' | System           | 09 Oct 2020 03:02:59 |

**US3902021**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(12)**

**Generated On: 10 Jun 2021 10:17:24**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| User entered '11 Oct 2020 11:59' | System           | 09 Oct 2020 03:02:59 |



**US3902021**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 10:17:24**

[Was Contact Attempted?](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 14 Apr 2021 06:18:15 |
| User signature succeeded. | Murray Kimmel (b) (4)   | 30 Mar 2021 18:10:57 |
| User entered 'Yes (Y)'    | Taylor Atkinson (b) (4) | 07 Oct 2020 17:04:33 |

**US3902021**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 10:17:24**

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

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 14 Apr 2021 06:18:15 |
| User signature succeeded. | Murray Kimmel (b) (4)   | 30 Mar 2021 18:10:57 |
| User entered '7 Oct 2020' | Taylor Atkinson (b) (4) | 07 Oct 2020 17:04:33 |

**US3902021**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 10:17:24**

[Please select one status for the follow-up contact](#)

| Audit                                      | User                    | Time (GMT)           |
|--|-------------------------|----------------------|
| Data hard locked.                          | (b) (4), (b) (6)        | 14 Apr 2021 06:18:15 |
| User signature succeeded.                  | Murray Kimmel (b) (4)   | 30 Mar 2021 18:10:57 |
| User entered 'Contact Made (CONTACT MADE)' | Taylor Atkinson (b) (4) | 07 Oct 2020 17:04:33 |

US3902021

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:17:24

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 14 Apr 2021 06:18:15 |
| User signature succeeded. | Murray Kimmel (b) (4)   | 30 Mar 2021 18:10:57 |
| User entered empty.       | Taylor Atkinson (b) (4) | 07 Oct 2020 17:04:33 |

**US3902021**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 10:17:24**

[Is the participant continuing to the next visit?](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 14 Apr 2021 06:18:15 |
| User signature succeeded. | Murray Kimmel (b) (4)   | 30 Mar 2021 18:10:57 |
| User entered 'Yes (Y)'    | Taylor Atkinson (b) (4) | 07 Oct 2020 17:11:05 |

**US3902021**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 10:17:24**

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 06:18:15 |
| User entered 'I'  | System           | 07 Oct 2020 17:11:05 |

**US3902021**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 10:17:24**

[Was Contact Attempted?](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 14 Apr 2021 06:18:15 |
| User signature succeeded. | Murray Kimmel (b) (4) | 30 Mar 2021 18:10:57 |
| User entered 'Yes (Y)'    | Bram Swarr (b) (4)    | 13 Oct 2020 20:01:16 |

**US3902021**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 10:17:24**

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

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 14 Apr 2021 06:18:15 |
| User signature succeeded.  | Murray Kimmel (b) (4) | 30 Mar 2021 18:10:57 |
| User entered '13 Oct 2020' | Bram Swarr (b) (4)    | 13 Oct 2020 20:01:16 |



**US3902021**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 10:17:24**

[Please select one status for the follow-up contact](#)

| Audit                                      | User                  | Time (GMT)           |
|--|-----------------------|----------------------|
| Data hard locked.                          | (b) (4), (b) (6)      | 14 Apr 2021 06:18:15 |
| User signature succeeded.                  | Murray Kimmel (b) (4) | 30 Mar 2021 18:10:57 |
| User entered 'Contact Made (CONTACT MADE)' | Bram Swarr (b) (4)    | 13 Oct 2020 20:01:16 |

**US3902021**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 10:17:24**

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 14 Apr 2021 06:18:15 |
| User signature succeeded. | Murray Kimmel (b) (4) | 30 Mar 2021 18:10:57 |
| User entered empty.       | Bram Swarr (b) (4)    | 13 Oct 2020 20:01:16 |

**US3902021**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 10:17:24**

[Is the participant continuing to the next visit?](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 14 Apr 2021 06:18:15 |
| User signature succeeded. | Murray Kimmel (b) (4) | 30 Mar 2021 18:10:57 |
| User entered 'Yes (Y)'    | Bram Swarr (b) (4)    | 13 Oct 2020 20:01:22 |

**US3902021**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 10:17:24**

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 06:18:15 |
| User entered 'I'  | System           | 13 Oct 2020 20:01:22 |

US3902021

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:17:24

[Was Contact Attempted?](#)

| Audit   | User                    | Time (GMT)           |
|---|-------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)        | 14 Apr 2021 06:18:15 |
| User signature succeeded.   | Murray Kimmel (b) (4)   | 30 Mar 2021 18:10:57 |
| User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Re-Query: Immunogenicity form is blank for Visit 3 Day 57, however, there is a Visit 3 Day 57 Immunogenicity sample with a Collection Date of 27OCT2020, per GCL. Please clarify and update as appropriate' (Site from DM).  | (b) (4), (b) (6)        | 17 Dec 2020 17:19:35 |
| Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Re-Query: Immunogenicity form is blank for Visit 3 Day 57, however, there is a Visit 3 Day 57 Immunogenicity sample with a Collection Date of 27OCT2020, per GCL. Please clarify and update as appropriate' answered with 'Visit entered' (Site from DM).  | Taylor Atkinson (b) (4) | 16 Dec 2020 13:56:24 |
| User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Re-Query: Immunogenicity form is blank for Visit 3 Day 57, however, there is a Visit 3 Day 57 Immunogenicity sample with a Collection Date of 27OCT2020, per GCL. Please clarify and update as appropriate' (Site from DM).  | (b) (4), (b) (6)        | 14 Dec 2020 13:33:29 |
| User closed query 'Per GCL Lab Reconciliation: Immunogenicity form is blank for Visit 3 Day 57, however, there is a Visit 3 Day 57 Immunogenicity sample with a Collection Date of 27OCT2020, per GCL. Please clarify and update as appropriate. ' (Site from DM).  | (b) (4), (b) (6)        | 14 Dec 2020 13:33:29 |
| Query 'Per GCL Lab Reconciliation: Immunogenicity form is blank for Visit 3 Day 57, however, there is a Visit 3 Day 57 Immunogenicity sample with a Collection Date of 27OCT2020, per GCL. Please clarify and update as appropriate. ' answered with 'site confirms samples were shipped, and received nov12. please wait to query these as samples go out regularly' (Site from DM). | Bram Swarr (b) (4)      | 12 Dec 2020 16:18:51 |

**US3902021**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 10:17:24**

[Was Contact Attempted?](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| User opened query 'Per GCL Lab Reconciliation: Immunogenicity form is blank for Visit 3 Day 57, however, there is a Visit 3 Day 57 Immunogenicity sample with a Collection Date of 27OCT2020, per GCL. Please clarify and update as appropriate. ' (Site from DM). | (b) (4), (b) (6) | 09 Nov 2020 18:36:28 |
| User entered 'Yes (Y)'   | (b) (4), (b) (6) | 23 Oct 2020 15:55:40 |

**US3902021**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 10:17:24**

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

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 14 Apr 2021 06:18:15 |
| User signature succeeded.  | Murray Kimmel (b) (4) | 30 Mar 2021 18:10:57 |
| User entered '22 Oct 2020' | (b) (4), (b) (6)      | 23 Oct 2020 15:55:40 |

**US3902021**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 10:17:24**

[Please select one status for the follow-up contact](#)

| Audit                                      | User                  | Time (GMT)           |
|--|-----------------------|----------------------|
| Data hard locked.                          | (b) (4), (b) (6)      | 14 Apr 2021 06:18:15 |
| User signature succeeded.                  | Murray Kimmel (b) (4) | 30 Mar 2021 18:10:57 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4), (b) (6)      | 23 Oct 2020 15:55:40 |



**US3902021**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 10:17:24**

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 14 Apr 2021 06:18:15 |
| User signature succeeded. | Murray Kimmel (b) (4) | 30 Mar 2021 18:10:57 |
| User entered empty.       | (b) (4), (b) (6)      | 23 Oct 2020 15:55:40 |

**US3902021**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 10:17:24**

[Is the participant continuing to the next visit?](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 14 Apr 2021 06:18:15 |
| User signature succeeded. | Murray Kimmel (b) (4) | 30 Mar 2021 18:10:57 |
| User entered 'Yes (Y)'    | (b) (4), (b) (6)      | 23 Oct 2020 15:55:49 |

**US3902021**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 10:17:24**

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 06:18:15 |
| User entered 'I'  | System           | 23 Oct 2020 15:55:49 |

**US3902021**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 10:17:24**

[Was this visit performed?](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 14 Apr 2021 06:18:59 |
| User signature succeeded. | Murray Kimmel (b) (4) | 30 Mar 2021 18:11:36 |
| User entered 'Yes (Y)'    | (b) (4), (b) (6)      | 15 Dec 2020 17:33:44 |

**US3902021**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 10:17:24**

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

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 14 Apr 2021 06:18:59 |
| User signature succeeded.  | Murray Kimmel (b) (4) | 30 Mar 2021 18:11:36 |
| User entered '27 Oct 2020' | (b) (4), (b) (6)      | 15 Dec 2020 17:33:44 |

**US3902021**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 10:17:24**

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

| Audit                          | User                  | Time (GMT)           |
|--------------------------------|-----------------------|----------------------|
| Data hard locked.              | (b) (4), (b) (6)      | 14 Apr 2021 06:18:59 |
| User signature succeeded.      | Murray Kimmel (b) (4) | 30 Mar 2021 18:11:36 |
| User entered 'Clinic (Clinic)' | (b) (4), (b) (6)      | 15 Dec 2020 17:33:44 |

**US3902021**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 10:17:24**

[Folder OID](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| Data hard locked.     | (b) (4), (b) (6) | 14 Apr 2021 06:18:59 |
| User entered 'VISIT3' | System           | 15 Dec 2020 17:33:44 |

**US3902021**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 10:17:24**

[Were vital signs assessed?](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 14 Apr 2021 06:18:59 |
| User signature succeeded. | Murray Kimmel (b) (4) | 30 Mar 2021 18:11:36 |
| User entered 'No (N)'     | (b) (4), (b) (6)      | 15 Dec 2020 17:34:24 |



**US3902021**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 10:17:24**

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

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 14 Apr 2021 06:18:59 |
| User signature succeeded. | Murray Kimmel (b) (4) | 30 Mar 2021 18:11:36 |
| User entered empty.       | (b) (4), (b) (6)      | 15 Dec 2020 17:34:24 |

**US3902021**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 10:17:24**

**Time of assessment (00:00-23:59)**

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 14 Apr 2021 06:18:59 |
| User signature succeeded. | Murray Kimmel (b) (4) | 30 Mar 2021 18:11:36 |
| User entered empty.       | (b) (4), (b) (6)      | 15 Dec 2020 17:34:24 |

**US3902021**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 10:17:24**

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 14 Apr 2021 06:18:59 |
| User entered empty. | System           | 15 Dec 2020 17:34:24 |

**US3902021**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 10:17:24**

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

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 14 Apr 2021 06:18:59 |
| User signature succeeded. | Murray Kimmel (b) (4) | 30 Mar 2021 18:11:36 |
| User entered empty.       | (b) (4), (b) (6)      | 15 Dec 2020 17:34:24 |

**US3902021**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 10:17:24**

[Route of measurement](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 14 Apr 2021 06:18:59 |
| User signature succeeded. | Murray Kimmel (b) (4) | 30 Mar 2021 18:11:36 |
| User entered empty.       | (b) (4), (b) (6)      | 15 Dec 2020 17:34:24 |

**US3902021**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 10:17:24**

[If Other, specify](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 14 Apr 2021 06:18:59 |
| User signature succeeded. | Murray Kimmel (b) (4) | 30 Mar 2021 18:11:36 |
| User entered empty.       | (b) (4), (b) (6)      | 15 Dec 2020 17:34:24 |

**US3902021**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 10:17:24**

[Pulse \(xxx\)](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 14 Apr 2021 06:18:59 |
| User signature succeeded. | Murray Kimmel (b) (4) | 30 Mar 2021 18:11:36 |
| User entered empty.       | (b) (4), (b) (6)      | 15 Dec 2020 17:34:24 |

**US3902021**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 10:17:24**

[Pulse units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 14 Apr 2021 06:18:59 |
| User entered empty. | System           | 15 Dec 2020 17:34:24 |



US3902021

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:17:24

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

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 14 Apr 2021 06:18:59 |
| User signature succeeded. | Murray Kimmel (b) (4) | 30 Mar 2021 18:11:36 |
| User entered empty.       | (b) (4), (b) (6)      | 15 Dec 2020 17:34:24 |

**US3902021**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 10:17:24**

[Respiratory Rate units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 14 Apr 2021 06:18:59 |
| User entered empty. | System           | 15 Dec 2020 17:34:24 |

**US3902021**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 10:17:24**

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

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 14 Apr 2021 06:18:59 |
| User signature succeeded. | Murray Kimmel (b) (4) | 30 Mar 2021 18:11:36 |
| User entered empty.       | (b) (4), (b) (6)      | 15 Dec 2020 17:34:24 |

**US3902021**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 10:17:24**

[Systolic Blood Pressure units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 14 Apr 2021 06:18:59 |
| User entered empty. | System           | 15 Dec 2020 17:34:24 |

**US3902021**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 10:17:24**

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

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 14 Apr 2021 06:18:59 |
| User signature succeeded. | Murray Kimmel (b) (4) | 30 Mar 2021 18:11:36 |
| User entered empty.       | (b) (4), (b) (6)      | 15 Dec 2020 17:34:24 |

**US3902021**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 10:17:24**

[Diastolic Blood Pressure units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 14 Apr 2021 06:18:59 |
| User entered empty. | System           | 15 Dec 2020 17:34:24 |

**US3902021**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 10:17:24**

[Height \(derived\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 06:18:59 |
|                   |                  |                      |

**US3902021**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 10:17:24**

[Weight \(derived\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 06:18:59 |
|                   |                  |                      |



US3902021

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:17:24

[Was the physical examination performed?](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 14 Apr 2021 06:18:59 |
| User signature succeeded. | Murray Kimmel (b) (4) | 30 Mar 2021 18:11:36 |
| User entered 'No (N)'     | (b) (4), (b) (6)      | 15 Dec 2020 17:34:30 |

**US3902021**

**Folder: Visit 3 Day 57 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 10:17:24**

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

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 14 Apr 2021 06:18:59 |
| User signature succeeded. | Murray Kimmel (b) (4) | 30 Mar 2021 18:11:36 |
| User entered empty.       | (b) (4), (b) (6)      | 15 Dec 2020 17:34:30 |

**US3902021**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 10:17:24**

[Was the sample collected?](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 14 Apr 2021 06:18:59 |
| User signature succeeded. | Murray Kimmel (b) (4) | 30 Mar 2021 18:11:36 |
| User entered 'Yes (Y)'    | (b) (4), (b) (6)      | 15 Dec 2020 17:34:43 |

**US3902021**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 10:17:24**

**Collection date** (*dd MMM yyyy*)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 14 Apr 2021 06:18:59 |
| User signature succeeded.  | Murray Kimmel (b) (4) | 30 Mar 2021 18:11:36 |
| User entered '27 Oct 2020' | (b) (4), (b) (6)      | 15 Dec 2020 17:34:43 |

**US3902021**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 10:17:24**

[Collection time \(00:00-23:59\)](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 14 Apr 2021 06:18:59 |
| User signature succeeded. | Murray Kimmel (b) (4) | 30 Mar 2021 18:11:36 |
| User entered '14:44'      | (b) (4), (b) (6)      | 15 Dec 2020 17:34:43 |

**US3902021**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 10:17:24**

[Collection date and time \(derived\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 14 Apr 2021 06:18:59 |
| User entered '27 Oct 2020 14:44' | System           | 15 Dec 2020 17:34:43 |

**US3902021**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 10:17:24**

[Is the participant continuing to the next visit?](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 14 Apr 2021 06:18:15 |
| User signature succeeded. | Murray Kimmel (b) (4) | 30 Mar 2021 18:11:36 |
| User entered 'Yes (Y)'    | (b) (4), (b) (6)      | 15 Dec 2020 17:38:34 |

**US3902021**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 10:17:24**

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 06:18:15 |
| User entered 'I'  | System           | 15 Dec 2020 17:38:34 |



**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

**TIMEPOINT**

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| Data hard locked.     | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| Data entry locked.    | System           | 02 Sep 2020 22:51:19 |
| User entered 'Day 64' | System           | 02 Sep 2020 22:51:19 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[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) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-11-02T07:11:34', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: 'edf5b1b2-faa1-4928-9d03-62e9babf13eb' User entered 'No (N)' | System           | 02 Nov 2020 12:11:51 |
|  | System           | 02 Nov 2020 12:11:51 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

Have you been exposed to someone with 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) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-11-02T07:11:44', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: 'edf5b1b2-faa1-4928-9d03-62e9babf13eb' User entered 'No (N)' | System           | 02 Nov 2020 12:11:51 |
|  | System           | 02 Nov 2020 12:11:51 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Date and time of submission](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-11-02T07:11:49', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: 'edf5b1b2-faa1-4928-9d03-62e9babf13eb' User entered '02 Nov 2020 07:11:49' | System           | 02 Nov 2020 12:11:51 |
|  | System           | 02 Nov 2020 12:11:51 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| Data entry locked.               | System           | 02 Sep 2020 22:51:19 |
| User entered '02 Nov 2020 00:01' | System           | 02 Sep 2020 22:51:19 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| Data entry locked.               | System           | 02 Sep 2020 22:51:19 |
| User entered '06 Nov 2020 23:59' | System           | 02 Sep 2020 22:51:19 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

**TIMEPOINT**

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| Data hard locked.     | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| Data entry locked.    | System           | 02 Sep 2020 22:51:19 |
| User entered 'Day 71' | System           | 02 Sep 2020 22:51:19 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[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) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-11-09T07:51:09', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: 'd938e189-9f26-4100-a213-3116600dd78d' | System           | 09 Nov 2020 12:51:18 |
| User entered 'No (N)'  | System           | 09 Nov 2020 12:51:18 |



**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

Have you been exposed to someone with 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) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-11-09T07:51:13', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: 'd938e189-9f26-4100-a213-3116600dd78d' | System           | 09 Nov 2020 12:51:18 |
| User entered 'No (N)'  | System           | 09 Nov 2020 12:51:18 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Date and time of submission](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-11-09T07:51:16', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: 'd938e189-9f26-4100-a213-3116600dd78d' User entered '09 Nov 2020 07:51:16' | System           | 09 Nov 2020 12:51:18 |
|  | System           | 09 Nov 2020 12:51:18 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| Data entry locked.               | System           | 02 Sep 2020 22:51:19 |
| User entered '09 Nov 2020 00:01' | System           | 02 Sep 2020 22:51:19 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| Data entry locked.               | System           | 02 Sep 2020 22:51:19 |
| User entered '13 Nov 2020 23:59' | System           | 02 Sep 2020 22:51:19 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

**TIMEPOINT**

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| Data hard locked.     | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| Data entry locked.    | System           | 02 Sep 2020 22:51:19 |
| User entered 'Day 78' | System           | 02 Sep 2020 22:51:19 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[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) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-11-16T14:53:09', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '32a3dfd7-5f88-4452-a4ee-1f388f444298' | System           | 16 Nov 2020 19:53:17 |
| User entered 'No (N)'  | System           | 16 Nov 2020 19:53:17 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

Have you been exposed to someone with 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) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-11-16T14:53:11', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '32a3dfd7-5f88-4452-a4ee-1f388f444298' | System           | 16 Nov 2020 19:53:17 |
| User entered 'No (N)'  | System           | 16 Nov 2020 19:53:17 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Date and time of submission](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-11-16T14:53:13', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '32a3dfd7-5f88-4452-a4ee-1f388f444298' User entered '16 Nov 2020 14:53:13' | System           | 16 Nov 2020 19:53:17 |
|  | System           | 16 Nov 2020 19:53:17 |



**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| Data entry locked.               | System           | 02 Sep 2020 22:51:19 |
| User entered '16 Nov 2020 00:01' | System           | 02 Sep 2020 22:51:19 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 27 Mar 2021 19:18:00 |
| Data entry locked.               | System           | 02 Sep 2020 22:51:19 |
| User entered '20 Nov 2020 23:59' | System           | 02 Sep 2020 22:51:19 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

**TIMEPOINT**

| Audit                                    | User   | Time (GMT)           |
|--|--------|----------------------|
| Amendment Manager: Data entry locked.    | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered 'Day 82' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered '20 Nov 2020 00:01' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered '24 Nov 2020 23:59' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

**TIMEPOINT**

| Audit                                    | User   | Time (GMT)           |
|--|--------|----------------------|
| Amendment Manager: Data entry locked.    | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered 'Day 89' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[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 (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-11-30T00:04:20', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '0a38dd28-38c5-4fc7-9624-3dd11d86ca45' User entered 'No (N)' | System | 30 Nov 2020 05:04:29 |
|  | System | 30 Nov 2020 05:04:29 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

Have you been exposed to someone with 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 (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-11-30T00:04:23', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '0a38dd28-38c5-4fc7-9624-3dd11d86ca45' | System | 30 Nov 2020 05:04:29 |
| User entered 'No (N)'  | System | 30 Nov 2020 05:04:29 |



**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-11-30T00:04:26', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '0a38dd28-38c5-4fc7-9624-3dd11d86ca45' User entered '30 Nov 2020 00:04:26' | System | 30 Nov 2020 05:04:29 |
|  | System | 30 Nov 2020 05:04:29 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered '27 Nov 2020 00:01' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered '01 Dec 2020 23:59' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

**TIMEPOINT**

| Audit                                    | User   | Time (GMT)           |
|--|--------|----------------------|
| Amendment Manager: Data entry locked.    | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered 'Day 96' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[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 (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-12-04T07:22:52', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '0d6b840a-9cda-47c1-9eb4-886e072946c3' | System | 04 Dec 2020 12:23:07 |
| User entered 'No (N)'  | System | 04 Dec 2020 12:23:07 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

Have you been exposed to someone with 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 (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-12-04T07:22:56', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '0d6b840a-9cda-47c1-9eb4-886e072946c3' | System | 04 Dec 2020 12:23:07 |
| User entered 'No (N)'  | System | 04 Dec 2020 12:23:07 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-12-04T07:23:03', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '0d6b840a-9cda-47c1-9eb4-886e072946c3' User entered '04 Dec 2020 07:23:03' | System | 04 Dec 2020 12:23:07 |
|  | System | 04 Dec 2020 12:23:07 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered '04 Dec 2020 00:01' | System | 20 Nov 2020 02:58:42 |



**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered '08 Dec 2020 23:59' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered 'Day 103' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[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 (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-12-11T11:02:22', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: 'f2757839-d233-486c-9c74-f091445e7004' | System | 11 Dec 2020 16:02:31 |
| User entered 'No (N)'  | System | 11 Dec 2020 16:02:31 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

Have you been exposed to someone with 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 (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-12-11T11:02:27', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: 'f2757839-d233-486c-9c74-f091445e7004' | System | 11 Dec 2020 16:02:31 |
| User entered 'No (N)'  | System | 11 Dec 2020 16:02:31 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-12-11T11:02:29', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: 'f2757839-d233-486c-9c74-f091445e7004' User entered '11 Dec 2020 11:02:29' | System | 11 Dec 2020 16:02:31 |
|  | System | 11 Dec 2020 16:02:31 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered '11 Dec 2020 00:01' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered '15 Dec 2020 23:59' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered 'Day 110' | System | 20 Nov 2020 02:58:42 |



**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[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 (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-12-18T07:40:44', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '8db59423-5554-45af-863a-bc3e18f2d279' | System | 18 Dec 2020 12:40:51 |
| User entered 'No (N)'  | System | 18 Dec 2020 12:40:51 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

Have you been exposed to someone with 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 (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-12-18T07:40:47', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '8db59423-5554-45af-863a-bc3e18f2d279' | System | 18 Dec 2020 12:40:51 |
| User entered 'No (N)'  | System | 18 Dec 2020 12:40:51 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-12-18T07:40:49', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '8db59423-5554-45af-863a-bc3e18f2d279' User entered '18 Dec 2020 07:40:49' | System | 18 Dec 2020 12:40:51 |
|  | System | 18 Dec 2020 12:40:51 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered '18 Dec 2020 00:01' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered '22 Dec 2020 23:59' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered 'Day 117' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[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 (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-12-25T08:59:55', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '19cf1aed-102b-4cd8-a72a-ae563cf31254' | System | 25 Dec 2020 14:00:44 |
| User entered 'No (N)'  | System | 25 Dec 2020 14:00:44 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Have you been exposed to someone with 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 (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-12-25T09:00:18', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '19cf1aed-102b-4cd8-a72a-ae563cf31254' | System | 25 Dec 2020 14:00:44 |
| User entered 'No (N)'  | System | 25 Dec 2020 14:00:44 |



**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2020-12-25T09:00:41', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '19cf1aed-102b-4cd8-a72a-ae563cf31254' User entered '25 Dec 2020 09:00:41' | System | 25 Dec 2020 14:00:44 |
|  | System | 25 Dec 2020 14:00:44 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered '25 Dec 2020 00:01' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered '29 Dec 2020 23:59' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered 'Day 124' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[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 (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2021-01-02T08:23:14', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: 'b3f2c0dd-0642-462d-966f-3f76accf9643' | System | 02 Jan 2021 14:23:22 |
| User entered 'No (N)'  | System | 02 Jan 2021 14:23:22 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

Have you been exposed to someone with 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 (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2021-01-02T08:23:17', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: 'b3f2c0dd-0642-462d-966f-3f76accf9643' | System | 02 Jan 2021 14:23:22 |
| User entered 'No (N)'  | System | 02 Jan 2021 14:23:22 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2021-01-02T08:23:20', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: 'b3f2c0dd-0642-462d-966f-3f76accf9643' User entered '02 Jan 2021 08:23:20' | System | 02 Jan 2021 14:23:22 |
|  | System | 02 Jan 2021 14:23:22 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered '01 Jan 2021 00:01' | System | 20 Nov 2020 02:58:42 |



**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered '05 Jan 2021 23:59' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered 'Day 131' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[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 (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2021-01-08T16:10:58', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '8c66cc0a-6c05-4571-8436-25df7946a2c7' | System | 08 Jan 2021 21:11:06 |
| User entered 'No (N)'  | System | 08 Jan 2021 21:11:06 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

Have you been exposed to someone with 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 (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2021-01-08T16:11:00', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '8c66cc0a-6c05-4571-8436-25df7946a2c7' | System | 08 Jan 2021 21:11:06 |
| User entered 'No (N)'  | System | 08 Jan 2021 21:11:06 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2021-01-08T16:11:02', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '8c66cc0a-6c05-4571-8436-25df7946a2c7' User entered '08 Jan 2021 16:11:02' | System | 08 Jan 2021 21:11:06 |
|  | System | 08 Jan 2021 21:11:06 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered '08 Jan 2021 00:01' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered '12 Jan 2021 23:59' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered 'Day 138' | System | 20 Nov 2020 02:58:42 |



**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[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 (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2021-01-15T07:54:21', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: 'a7c7b956-3777-49d8-a5c9-8d0c499a22f0' | System | 15 Jan 2021 12:54:29 |
| User entered 'No (N)'  | System | 15 Jan 2021 12:54:29 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

Have you been exposed to someone with 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 (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2021-01-15T07:54:23', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: 'a7c7b956-3777-49d8-a5c9-8d0c499a22f0' | System | 15 Jan 2021 12:54:29 |
| User entered 'No (N)'  | System | 15 Jan 2021 12:54:29 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2021-01-15T07:54:26', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: 'a7c7b956-3777-49d8-a5c9-8d0c499a22f0' User entered '15 Jan 2021 07:54:26' | System | 15 Jan 2021 12:54:29 |
|  | System | 15 Jan 2021 12:54:29 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered '15 Jan 2021 00:01' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered '19 Jan 2021 23:59' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered 'Day 145' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[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 (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2021-01-22T14:07:56', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: 'f0a9d45f-1290-426f-b861-b534b70ebca7' | System | 22 Jan 2021 19:08:37 |
| User entered 'No (N)'  | System | 22 Jan 2021 19:08:37 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

Have you been exposed to someone with 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 (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2021-01-22T14:07:58', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: 'f0a9d45f-1290-426f-b861-b534b70ebca7' | System | 22 Jan 2021 19:08:37 |
| User entered 'No (N)'  | System | 22 Jan 2021 19:08:37 |



**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2021-01-22T14:08:04', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: 'f0a9d45f-1290-426f-b861-b534b70ebca7' User entered '22 Jan 2021 14:08:04' | System | 22 Jan 2021 19:08:37 |
|  | System | 22 Jan 2021 19:08:37 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered '22 Jan 2021 00:01' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered '26 Jan 2021 23:59' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered 'Day 152' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[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 (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2021-02-02T15:48:14', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '5242c369-d8c4-48f0-8dcf-8beaadc96914' User entered 'No (N)' | System | 02 Feb 2021 20:48:23 |
|  | System | 02 Feb 2021 20:48:23 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

Have you been exposed to someone with 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 (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2021-02-02T15:48:17', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '5242c369-d8c4-48f0-8dcf-8beaadc96914' User entered 'No (N)' | System | 02 Feb 2021 20:48:23 |
|  | System | 02 Feb 2021 20:48:23 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2021-02-02T15:48:19', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '5242c369-d8c4-48f0-8dcf-8beaedc96914' User entered '02 Feb 2021 15:48:19' | System | 02 Feb 2021 20:48:23 |
|  | System | 02 Feb 2021 20:48:23 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered '29 Jan 2021 00:01' | System | 20 Nov 2020 02:58:42 |



**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered '02 Feb 2021 23:59' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered 'Day 159' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[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 (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2021-02-05T23:47:30', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: 'cd8fc46a-7f58-446e-8436-52e36c9b5226' | System | 06 Feb 2021 04:47:57 |
| User entered 'No (N)'  | System | 06 Feb 2021 04:47:57 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Have you been exposed to someone with 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 (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2021-02-05T23:47:34', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: 'cd8fc46a-7f58-446e-8436-52e36c9b5226' | System | 06 Feb 2021 04:47:57 |
| User entered 'No (N)'  | System | 06 Feb 2021 04:47:57 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2021-02-05T23:47:37', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: 'cd8fc46a-7f58-446e-8436-52e36c9b5226' User entered '05 Feb 2021 23:47:37' | System | 06 Feb 2021 04:47:57 |
|  | System | 06 Feb 2021 04:47:57 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered '05 Feb 2021 00:01' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered '09 Feb 2021 23:59' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered 'Day 166' | System | 20 Nov 2020 02:58:42 |



**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[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 (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2021-02-12T12:45:54', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '4806ffd9-10b5-4dc9-9327-23b3a81df7a9' User entered 'No (N)' | System | 12 Feb 2021 17:46:04 |
|  | System | 12 Feb 2021 17:46:04 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Have you been exposed to someone with 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 (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2021-02-12T12:45:57', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '4806ffd9-10b5-4dc9-9327-23b3a81df7a9' User entered 'No (N)' | System | 12 Feb 2021 17:46:04 |
|  | System | 12 Feb 2021 17:46:04 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2021-02-12T12:46:01', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '4806ffd9-10b5-4dc9-9327-23b3a81df7a9' User entered '12 Feb 2021 12:46:01' | System | 12 Feb 2021 17:46:04 |
|  | System | 12 Feb 2021 17:46:04 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered '12 Feb 2021 00:01' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered '16 Feb 2021 23:59' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered 'Day 173' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[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 (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2021-02-19T15:45:26', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '4400c5ba-95e5-4321-9e80-1ae5d22f4ccf' User entered 'Yes (Y)' | System | 19 Feb 2021 22:06:16 |
|   | System | 19 Feb 2021 22:06:16 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Have you been exposed to someone with 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 (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2021-02-19T15:45:29', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '4400c5ba-95e5-4321-9e80-1ae5d22f4ccf' User entered 'No (N)' | System | 19 Feb 2021 22:06:16 |
|  | System | 19 Feb 2021 22:06:16 |



**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[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 (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2021-02-19T15:45:35', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '4400c5ba-95e5-4321-9e80-1ae5d22f4ccf' User entered 'No (N)' | System | 19 Feb 2021 22:06:16 |
|  | System | 19 Feb 2021 22:06:16 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[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 (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2021-02-19T15:45:42', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '4400c5ba-95e5-4321-9e80-1ae5d22f4ccf' User entered 'Yes (Y)' | System | 19 Feb 2021 22:06:16 |
|   | System | 19 Feb 2021 22:06:16 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Please 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 (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2021-02-19T15:46:10', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '4400c5ba-95e5-4321-9e80-1ae5d22f4ccf' | System | 19 Feb 2021 22:06:16 |
| User entered 'I confirm I have read this message and will call the study clinic immediately (9)'   | System | 19 Feb 2021 22:06:16 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2021-02-19T15:46:14', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '4400c5ba-95e5-4321-9e80-1ae5d22f4ccf' User entered '19 Feb 2021 15:46:14' | System | 19 Feb 2021 22:06:16 |
|  | System | 19 Feb 2021 22:06:16 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered '19 Feb 2021 00:01' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered '23 Feb 2021 23:59' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered 'Day 180' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[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 (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2021-02-28T19:01:55-05:00', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '3ddaa606-93f4-43f5-85cf-e32f0fbaa221' | System | 01 Mar 2021 00:04:45 |
| User entered 'No (N)'  | System | 01 Mar 2021 00:04:45 |



**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Have you been exposed to someone with 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 (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2021-02-28T19:01:58-05:00', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '3ddaa606-93f4-43f5-85cf-e32f0fbaa221' | System | 01 Mar 2021 00:04:45 |
| User entered 'No (N)'  | System | 01 Mar 2021 00:04:45 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2021-02-28T19:02:00-05:00', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '3ddaa606-93f4-43f5-85cf-e32f0fbaa221' User entered '28 Feb 2021 19:02:00' | System | 01 Mar 2021 00:04:45 |
|  | System | 01 Mar 2021 00:04:45 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered '26 Feb 2021 00:01' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered '02 Mar 2021 23:59' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered 'Day 187' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[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 (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2021-03-09T08:51:16-05:00', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '520c82fe-d7e7-48a6-98f9-31bc233485bf' | System | 09 Mar 2021 13:51:25 |
| User entered 'No (N)'  | System | 09 Mar 2021 13:51:25 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

Have you been exposed to someone with 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 (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2021-03-09T08:51:18-05:00', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '520c82fe-d7e7-48a6-98f9-31bc233485bf' User entered 'No (N)' | System | 09 Mar 2021 13:51:25 |
|  | System | 09 Mar 2021 13:51:25 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2021-03-09T08:51:20-05:00', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '520c82fe-d7e7-48a6-98f9-31bc233485bf' | System | 09 Mar 2021 13:51:25 |
| User entered '09 Mar 2021 08:51:20'  | System | 09 Mar 2021 13:51:25 |



**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered '05 Mar 2021 00:01' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered '09 Mar 2021 23:59' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered 'Day 194' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[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 (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2021-03-12T06:51:28-05:00', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '883cf337-0e48-4fa2-a6e2-c8fdb0838dce' | System | 12 Mar 2021 11:51:37 |
| User entered 'No (N)'  | System | 12 Mar 2021 11:51:37 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

Have you been exposed to someone with 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 (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2021-03-12T06:51:31-05:00', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '883cf337-0e48-4fa2-a6e2-c8fdb0838dce' | System | 12 Mar 2021 11:51:37 |
| User entered 'No (N)'  | System | 12 Mar 2021 11:51:37 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2021-03-12T06:51:34-05:00', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '883cf337-0e48-4fa2-a6e2-c8fdb0838dce' | System | 12 Mar 2021 11:51:37 |
| User entered '12 Mar 2021 06:51:34'  | System | 12 Mar 2021 11:51:37 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered '12 Mar 2021 00:01' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered '16 Mar 2021 23:59' | System | 20 Nov 2020 02:58:42 |



**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered 'Day 201' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[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 (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2021-03-19T11:09:59-04:00', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '41e309e3-b428-4d94-a57c-9523d002008c' | System | 19 Mar 2021 15:10:07 |
| User entered 'No (N)'  | System | 19 Mar 2021 15:10:07 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

Have you been exposed to someone with 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 (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2021-03-19T11:10:01-04:00', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '41e309e3-b428-4d94-a57c-9523d002008c' | System | 19 Mar 2021 15:10:07 |
| User entered 'No (N)'  | System | 19 Mar 2021 15:10:07 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2021-03-19T11:10:03-04:00', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '41e309e3-b428-4d94-a57c-9523d002008c' | System | 19 Mar 2021 15:10:07 |
| User entered '19 Mar 2021 11:10:03'  | System | 19 Mar 2021 15:10:07 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered '19 Mar 2021 00:01' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered '23 Mar 2021 23:59' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered 'Day 208' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[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 (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2021-03-26T09:41:24-04:00', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '160af98c-38fc-462b-bbed-f265cd3e5551' | System | 26 Mar 2021 13:41:33 |
| User entered 'No (N)'  | System | 26 Mar 2021 13:41:33 |



**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Have you been exposed to someone with 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 (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2021-03-26T09:41:28-04:00', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '160af98c-38fc-462b-bbed-f265cd3e5551' | System | 26 Mar 2021 13:41:33 |
| User entered 'No (N)'  | System | 26 Mar 2021 13:41:33 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2021-03-26T09:41:30-04:00', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '160af98c-38fc-462b-bbed-f265cd3e5551' | System | 26 Mar 2021 13:41:33 |
| User entered '26 Mar 2021 09:41:30'  | System | 26 Mar 2021 13:41:33 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered '26 Mar 2021 00:01' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered '30 Mar 2021 23:59' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered 'Day 215' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[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 (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2021-04-03T11:10:29-05:00', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '09c0dea1-669c-4519-b5e1-ebcd70fa33af' | System | 03 Apr 2021 16:12:27 |
| User entered 'No (N)'  | System | 03 Apr 2021 16:12:27 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Have you been exposed to someone with 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 (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2021-04-03T11:10:32-05:00', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '09c0dea1-669c-4519-b5e1-ebcd70fa33af' | System | 03 Apr 2021 16:12:27 |
| User entered 'No (N)'  | System | 03 Apr 2021 16:12:27 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2021-04-03T11:10:50-05:00', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '09c0dea1-669c-4519-b5e1-ebcd70fa33af' | System | 03 Apr 2021 16:12:27 |
| User entered '03 Apr 2021 11:10:50'  | System | 03 Apr 2021 16:12:27 |



**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered '02 Apr 2021 00:01' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered '06 Apr 2021 23:59' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered 'Day 222' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[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 (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2021-04-09T09:37:20-04:00', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '12ac5d8d-7b40-4df5-9c24-69afe311fca5' User entered 'No (N)' | System | 09 Apr 2021 13:37:32 |
|  | System | 09 Apr 2021 13:37:32 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

Have you been exposed to someone with 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 (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2021-04-09T09:37:25-04:00', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '12ac5d8d-7b40-4df5-9c24-69afe311fca5' User entered 'No (N)' | System | 09 Apr 2021 13:37:32 |
|  | System | 09 Apr 2021 13:37:32 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2021-04-09T09:37:27-04:00', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '12ac5d8d-7b40-4df5-9c24-69afe311fca5' | System | 09 Apr 2021 13:37:32 |
| User entered '09 Apr 2021 09:37:27'  | System | 09 Apr 2021 13:37:32 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered '09 Apr 2021 00:01' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered '13 Apr 2021 23:59' | System | 20 Nov 2020 02:58:42 |



**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered 'Day 229' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[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 (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2021-04-16T07:25:35-04:00', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '3bc4014f-961a-4d23-a896-081ea19ee0a6' | System | 16 Apr 2021 11:25:48 |
| User entered 'No (N)'  | System | 16 Apr 2021 11:25:48 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

Have you been exposed to someone with 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 (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2021-04-16T07:25:37-04:00', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '3bc4014f-961a-4d23-a896-081ea19ee0a6' | System | 16 Apr 2021 11:25:48 |
| User entered 'No (N)'  | System | 16 Apr 2021 11:25:48 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2021-04-16T07:25:43-04:00', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '3bc4014f-961a-4d23-a896-081ea19ee0a6' | System | 16 Apr 2021 11:25:48 |
| User entered '16 Apr 2021 07:25:43'  | System | 16 Apr 2021 11:25:48 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered '16 Apr 2021 00:01' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered '20 Apr 2021 23:59' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered 'Day 236' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[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 (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2021-04-23T07:03:39-04:00', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '0722fa3f-e1eb-45a2-982a-5874eee3921e' User entered 'No (N)' | System | 23 Apr 2021 11:03:47 |
|  | System | 23 Apr 2021 11:03:47 |



**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

Have you been exposed to someone with 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 (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2021-04-23T07:03:41-04:00', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '0722fa3f-e1eb-45a2-982a-5874eee3921e' | System | 23 Apr 2021 11:03:47 |
| User entered 'No (N)'  | System | 23 Apr 2021 11:03:47 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2021-04-23T07:03:44-04:00', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '0722fa3f-e1eb-45a2-982a-5874eee3921e' User entered '23 Apr 2021 07:03:44' | System | 23 Apr 2021 11:03:47 |
|  | System | 23 Apr 2021 11:03:47 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered '23 Apr 2021 00:01' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered '27 Apr 2021 23:59' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered 'Day 243' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[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 (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2021-04-30T21:49:56-04:00', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '4a318933-82b6-463e-821e-b81793b0dcdf' | System | 01 May 2021 01:50:09 |
| User entered 'No (N)'  | System | 01 May 2021 01:50:09 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

Have you been exposed to someone with 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 (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2021-04-30T21:49:59-04:00', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '4a318933-82b6-463e-821e-b81793b0dcdf' | System | 01 May 2021 01:50:09 |
| User entered 'No (N)'  | System | 01 May 2021 01:50:09 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Date and time of submission](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2021-04-30T21:50:01-04:00', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '4a318933-82b6-463e-821e-b81793b0dcd' | System | 01 May 2021 01:50:09 |
| User entered '30 Apr 2021 21:50:01'   | System | 01 May 2021 01:50:09 |



**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered '30 Apr 2021 00:01' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered '04 May 2021 23:59' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered 'Day 250' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered '07 May 2021 00:01' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered '11 May 2021 23:59' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered 'Day 257' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered '14 May 2021 00:01' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered '18 May 2021 23:59' | System | 20 Nov 2020 02:58:42 |



**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered 'Day 264' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered '21 May 2021 00:01' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered '25 May 2021 23:59' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered 'Day 271' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered '28 May 2021 00:01' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered '01 Jun 2021 23:59' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered 'Day 278' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered '04 Jun 2021 00:01' | System | 20 Nov 2020 02:58:42 |



**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered '08 Jun 2021 23:59' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered 'Day 285' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered '11 Jun 2021 00:01' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered '15 Jun 2021 23:59' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered 'Day 292' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered '18 Jun 2021 00:01' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered '22 Jun 2021 23:59' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered 'Day 299' | System | 20 Nov 2020 02:58:42 |



**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered '25 Jun 2021 00:01' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered '29 Jun 2021 23:59' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered 'Day 306' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered '02 Jul 2021 00:01' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered '06 Jul 2021 23:59' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered 'Day 313' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered '09 Jul 2021 00:01' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered '13 Jul 2021 23:59' | System | 20 Nov 2020 02:58:42 |



**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered 'Day 320' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered '16 Jul 2021 00:01' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered '20 Jul 2021 23:59' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered 'Day 327' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered '23 Jul 2021 00:01' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered '27 Jul 2021 23:59' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered 'Day 334' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered '30 Jul 2021 00:01' | System | 20 Nov 2020 02:58:42 |



**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered '03 Aug 2021 23:59' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered 'Day 341' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered '06 Aug 2021 00:01' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered '10 Aug 2021 23:59' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered 'Day 348' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered '13 Aug 2021 00:01' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered '17 Aug 2021 23:59' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered 'Day 355' | System | 20 Nov 2020 02:58:42 |



**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered '20 Aug 2021 00:01' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered '24 Aug 2021 23:59' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered 'Day 362' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered '27 Aug 2021 00:01' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered '31 Aug 2021 23:59' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered 'Day 369' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered '03 Sep 2021 00:01' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered '07 Sep 2021 23:59' | System | 20 Nov 2020 02:58:42 |



**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered 'Day 376' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered '10 Sep 2021 00:01' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered '14 Sep 2021 23:59' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered 'Day 383' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered '17 Sep 2021 00:01' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered '21 Sep 2021 23:59' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered 'Day 390' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered '24 Sep 2021 00:01' | System | 20 Nov 2020 02:58:42 |



**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered '28 Sep 2021 23:59' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered 'Day 397' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered '01 Oct 2021 00:01' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered '05 Oct 2021 23:59' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered 'Day 404' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered '08 Oct 2021 00:01' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered '12 Oct 2021 23:59' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered 'Day 411' | System | 20 Nov 2020 02:58:42 |



**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered '15 Oct 2021 00:01' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered '19 Oct 2021 23:59' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered 'Day 418' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered '22 Oct 2021 00:01' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered '26 Oct 2021 23:59' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered 'Day 425' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered '29 Oct 2021 00:01' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered '02 Nov 2021 23:59' | System | 20 Nov 2020 02:58:42 |



**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered 'Day 432' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered '05 Nov 2021 00:01' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered '09 Nov 2021 23:59' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered 'Day 439' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered '12 Nov 2021 00:01' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered '16 Nov 2021 23:59' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered 'Day 446' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered '19 Nov 2021 00:01' | System | 20 Nov 2020 02:58:42 |



**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered '23 Nov 2021 23:59' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered 'Day 453' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered '26 Nov 2021 00:01' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered '30 Nov 2021 23:59' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered 'Day 460' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered '03 Dec 2021 00:01' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered '07 Dec 2021 23:59' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered 'Day 467' | System | 20 Nov 2020 02:58:42 |



**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered '10 Dec 2021 00:01' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered '14 Dec 2021 23:59' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered 'Day 474' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered '17 Dec 2021 00:01' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered '21 Dec 2021 23:59' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered 'Day 481' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered '24 Dec 2021 00:01' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered '28 Dec 2021 23:59' | System | 20 Nov 2020 02:58:42 |



**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered 'Day 488' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered '31 Dec 2021 00:01' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered '04 Jan 2022 23:59' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered 'Day 495' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered '07 Jan 2022 00:01' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered '11 Jan 2022 23:59' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered 'Day 502' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered '14 Jan 2022 00:01' | System | 20 Nov 2020 02:58:42 |



**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered '18 Jan 2022 23:59' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered 'Day 509' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered '21 Jan 2022 00:01' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered '25 Jan 2022 23:59' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered 'Day 516' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered '28 Jan 2022 00:01' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered '01 Feb 2022 23:59' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered 'Day 523' | System | 20 Nov 2020 02:58:42 |



**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered '04 Feb 2022 00:01' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered '08 Feb 2022 23:59' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered 'Day 530' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered '11 Feb 2022 00:01' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered '15 Feb 2022 23:59' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered 'Day 537' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered '18 Feb 2022 00:01' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered '22 Feb 2022 23:59' | System | 20 Nov 2020 02:58:42 |



**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered 'Day 544' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered '25 Feb 2022 00:01' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered '01 Mar 2022 23:59' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered 'Day 551' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered '04 Mar 2022 00:01' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered '08 Mar 2022 23:59' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered 'Day 558' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered '11 Mar 2022 00:01' | System | 20 Nov 2020 02:58:42 |



**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered '15 Mar 2022 23:59' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered 'Day 565' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered '18 Mar 2022 00:01' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered '22 Mar 2022 23:59' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered 'Day 572' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered '25 Mar 2022 00:01' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered '29 Mar 2022 23:59' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered 'Day 579' | System | 20 Nov 2020 02:58:42 |



**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered '01 Apr 2022 00:01' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered '05 Apr 2022 23:59' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered 'Day 586' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered '08 Apr 2022 00:01' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered '12 Apr 2022 23:59' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered 'Day 593' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered '15 Apr 2022 00:01' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered '19 Apr 2022 23:59' | System | 20 Nov 2020 02:58:42 |



**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered 'Day 600' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered '22 Apr 2022 00:01' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered '26 Apr 2022 23:59' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered 'Day 607' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered '29 Apr 2022 00:01' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered '03 May 2022 23:59' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered 'Day 614' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered '06 May 2022 00:01' | System | 20 Nov 2020 02:58:42 |



**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered '10 May 2022 23:59' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered 'Day 621' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered '13 May 2022 00:01' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered '17 May 2022 23:59' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered 'Day 628' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered '20 May 2022 00:01' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered '24 May 2022 23:59' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered 'Day 635' | System | 20 Nov 2020 02:58:42 |



**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered '27 May 2022 00:01' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered '31 May 2022 23:59' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered 'Day 642' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered '03 Jun 2022 00:01' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered '07 Jun 2022 23:59' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered 'Day 649' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered '10 Jun 2022 00:01' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered '14 Jun 2022 23:59' | System | 20 Nov 2020 02:58:42 |



**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered 'Day 656' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered '17 Jun 2022 00:01' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered '21 Jun 2022 23:59' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered 'Day 663' | System | 20 Nov 2020 02:58:42 |

**US3902021**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered '24 Jun 2022 00:01' | System | 20 Nov 2020 02:58:42 |

**US3902021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered '28 Jun 2022 23:59' | System | 20 Nov 2020 02:58:42 |

**US3902021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered 'Day 670' | System | 20 Nov 2020 02:58:42 |

**US3902021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered '01 Jul 2022 00:01' | System | 20 Nov 2020 02:58:42 |



**US3902021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered '05 Jul 2022 23:59' | System | 20 Nov 2020 02:58:42 |

**US3902021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered 'Day 677' | System | 20 Nov 2020 02:58:42 |

**US3902021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered '08 Jul 2022 00:01' | System | 20 Nov 2020 02:58:42 |

**US3902021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered '12 Jul 2022 23:59' | System | 20 Nov 2020 02:58:42 |

**US3902021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered 'Day 684' | System | 20 Nov 2020 02:58:42 |

**US3902021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered '15 Jul 2022 00:01' | System | 20 Nov 2020 02:58:42 |

**US3902021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered '19 Jul 2022 23:59' | System | 20 Nov 2020 02:58:42 |

**US3902021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered 'Day 691' | System | 20 Nov 2020 02:58:42 |



**US3902021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered '22 Jul 2022 00:01' | System | 20 Nov 2020 02:58:42 |

**US3902021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered '26 Jul 2022 23:59' | System | 20 Nov 2020 02:58:42 |

**US3902021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered 'Day 698' | System | 20 Nov 2020 02:58:42 |

**US3902021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered '29 Jul 2022 00:01' | System | 20 Nov 2020 02:58:42 |

**US3902021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered '02 Aug 2022 23:59' | System | 20 Nov 2020 02:58:42 |

**US3902021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered 'Day 705' | System | 20 Nov 2020 02:58:42 |

**US3902021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered '05 Aug 2022 00:01' | System | 20 Nov 2020 02:58:42 |

**US3902021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered '09 Aug 2022 23:59' | System | 20 Nov 2020 02:58:42 |



**US3902021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered 'Day 712' | System | 20 Nov 2020 02:58:42 |

**US3902021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered '12 Aug 2022 00:01' | System | 20 Nov 2020 02:58:42 |

**US3902021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered '16 Aug 2022 23:59' | System | 20 Nov 2020 02:58:42 |

**US3902021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered 'Day 719' | System | 20 Nov 2020 02:58:42 |

**US3902021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered '19 Aug 2022 00:01' | System | 20 Nov 2020 02:58:42 |

**US3902021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered '23 Aug 2022 23:59' | System | 20 Nov 2020 02:58:42 |

**US3902021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered 'Day 726' | System | 20 Nov 2020 02:58:42 |

**US3902021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered '26 Aug 2022 00:01' | System | 20 Nov 2020 02:58:42 |



**US3902021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered '30 Aug 2022 23:59' | System | 20 Nov 2020 02:58:42 |

**US3902021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered 'Day 733' | System | 20 Nov 2020 02:58:42 |

**US3902021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered '02 Sep 2022 00:01' | System | 20 Nov 2020 02:58:42 |

**US3902021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered '06 Sep 2022 23:59' | System | 20 Nov 2020 02:58:42 |

**US3902021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered 'Day 740' | System | 20 Nov 2020 02:58:42 |

**US3902021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered '09 Sep 2022 00:01' | System | 20 Nov 2020 02:58:42 |

**US3902021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered '13 Sep 2022 23:59' | System | 20 Nov 2020 02:58:42 |

**US3902021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered 'Day 747' | System | 20 Nov 2020 02:58:42 |



**US3902021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered '16 Sep 2022 00:01' | System | 20 Nov 2020 02:58:42 |

**US3902021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered '20 Sep 2022 23:59' | System | 20 Nov 2020 02:58:42 |

**US3902021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered 'Day 754' | System | 20 Nov 2020 02:58:42 |

**US3902021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered '23 Sep 2022 00:01' | System | 20 Nov 2020 02:58:42 |

**US3902021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered '27 Sep 2022 23:59' | System | 20 Nov 2020 02:58:42 |

**US3902021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered 'Day 761' | System | 20 Nov 2020 02:58:42 |

**US3902021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered '30 Sep 2022 00:01' | System | 20 Nov 2020 02:58:42 |

**US3902021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered '04 Oct 2022 23:59' | System | 20 Nov 2020 02:58:42 |



**US3902021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered 'Day 768' | System | 20 Nov 2020 02:58:42 |

**US3902021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered '07 Oct 2022 00:01' | System | 20 Nov 2020 02:58:42 |

**US3902021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered '11 Oct 2022 23:59' | System | 20 Nov 2020 02:58:42 |

**US3902021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered 'Day 775' | System | 20 Nov 2020 02:58:42 |

**US3902021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered '14 Oct 2022 00:01' | System | 20 Nov 2020 02:58:42 |

**US3902021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered '18 Oct 2022 23:59' | System | 20 Nov 2020 02:58:42 |

**US3902021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered 'Day 782' | System | 20 Nov 2020 02:58:42 |

**US3902021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered '21 Oct 2022 00:01' | System | 20 Nov 2020 02:58:42 |



**US3902021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered '25 Oct 2022 23:59' | System | 20 Nov 2020 02:58:42 |

**US3902021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered 'Day 789' | System | 20 Nov 2020 02:58:42 |

**US3902021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered '28 Oct 2022 00:01' | System | 20 Nov 2020 02:58:42 |

**US3902021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered '01 Nov 2022 23:59' | System | 20 Nov 2020 02:58:42 |

**US3902021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered 'Day 796' | System | 20 Nov 2020 02:58:42 |

**US3902021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered '04 Nov 2022 00:01' | System | 20 Nov 2020 02:58:42 |

**US3902021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:17:24**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:58:42 |
| Amendment Manager: User entered '08 Nov 2022 23:59' | System | 20 Nov 2020 02:58:42 |

US3902021

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 10:17:24

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) | 24 Apr 2021 21:14:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2021-02-28T19:02:08-05:00', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '5e284384-1c44-4ce4-91ac-085e52654d00' | System           | 01 Mar 2021 00:05:03 |
| User entered 'No (N)'  | System           | 01 Mar 2021 00:05:03 |



**US3902021**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 10 Jun 2021 10:17:24**

[Date & Time of Submission](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 24 Apr 2021 21:14:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25C52621-95E7-4C1D-A3E0-35FBBAC68800)', Time: '2021-02-28T19:02:12-05:00', User OID: 'PatientReportedOutcome (US3902021)', ODM File OID: '5e284384-1c44-4ce4-91ac-085e52654d00' User entered '28 Feb 2021 19:02:12' | System           | 01 Mar 2021 00:05:03 |
|  | System           | 01 Mar 2021 00:05:03 |

**US3902021**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 10:17:24**

[Was Contact Attempted?](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 14 Apr 2021 06:18:15 |
| User signature succeeded. | Murray Kimmel (b) (4) | 30 Mar 2021 18:10:57 |
| User entered 'Yes (Y)'    | (b) (4), (b) (6)      | 15 Dec 2020 17:39:17 |

**US3902021**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 10:17:24**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 14 Apr 2021 06:18:15 |
| User signature succeeded.  | Murray Kimmel (b) (4) | 30 Mar 2021 18:10:57 |
| User entered '23 Nov 2020' | (b) (4), (b) (6)      | 15 Dec 2020 17:39:17 |

**US3902021**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 10:17:24**

[Please select one status for the follow-up contact](#)

| Audit                                      | User                  | Time (GMT)           |
|--|-----------------------|----------------------|
| Data hard locked.                          | (b) (4), (b) (6)      | 14 Apr 2021 06:18:15 |
| User signature succeeded.                  | Murray Kimmel (b) (4) | 30 Mar 2021 18:10:57 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4), (b) (6)      | 15 Dec 2020 17:39:17 |

**US3902021**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 10:17:24**

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 14 Apr 2021 06:18:15 |
| User signature succeeded. | Murray Kimmel (b) (4) | 30 Mar 2021 18:10:57 |
| User entered empty.       | (b) (4), (b) (6)      | 15 Dec 2020 17:39:17 |

**US3902021**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 10:17:24**

[Is the participant continuing to the next visit?](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 14 Apr 2021 06:18:15 |
| User signature succeeded. | Murray Kimmel (b) (4) | 30 Mar 2021 18:10:57 |
| User entered 'Yes (Y)'    | (b) (4), (b) (6)      | 15 Dec 2020 17:39:24 |

**US3902021**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 10:17:24**

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 06:18:15 |
| User entered 'I'  | System           | 15 Dec 2020 17:39:24 |

**US3902021**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 10:17:24**

[Was Contact Attempted?](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 27 Apr 2021 10:21:29 |
| User signature succeeded. | Murray Kimmel (b) (4) | 30 Mar 2021 18:10:57 |
| User entered 'Yes (Y)'    | (b) (4), (b) (6)      | 28 Dec 2020 21:16:48 |



**US3902021**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 10:17:24**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 27 Apr 2021 10:21:29 |
| User signature succeeded.  | Murray Kimmel (b) (4) | 30 Mar 2021 18:10:57 |
| User entered '28 Dec 2020' | (b) (4), (b) (6)      | 28 Dec 2020 21:16:48 |

**US3902021**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 10:17:24**

[Please select one status for the follow-up contact](#)

| Audit                                      | User                  | Time (GMT)           |
|--|-----------------------|----------------------|
| Data hard locked.                          | (b) (4), (b) (6)      | 27 Apr 2021 10:21:29 |
| User signature succeeded.                  | Murray Kimmel (b) (4) | 30 Mar 2021 18:10:57 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4), (b) (6)      | 28 Dec 2020 21:16:48 |

**US3902021**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 10:17:24**

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 27 Apr 2021 10:21:29 |
| User signature succeeded. | Murray Kimmel (b) (4) | 30 Mar 2021 18:10:57 |
| User entered empty.       | (b) (4), (b) (6)      | 28 Dec 2020 21:16:48 |

**US3902021**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 10:17:24**

[Is the participant continuing to the next visit?](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 27 Apr 2021 10:21:29 |
| User signature succeeded. | Murray Kimmel (b) (4) | 30 Mar 2021 18:10:57 |
| User entered 'Yes (Y)'    | (b) (4), (b) (6)      | 28 Dec 2020 21:16:55 |

**US3902021**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 10:17:24**

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 10:21:29 |
| User entered 'I'  | System           | 28 Dec 2020 21:16:55 |

**US3902021**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 10:17:24**

[Was Contact Attempted?](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 27 Apr 2021 10:21:29 |
| User signature succeeded. | Murray Kimmel (b) (4)   | 30 Mar 2021 18:10:57 |
| User entered 'Yes (Y)'    | Taylor Atkinson (b) (4) | 22 Feb 2021 22:49:20 |

**US3902021**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 10:17:24**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

| Audit                      | User                    | Time (GMT)           |
|----------------------------|-------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)        | 27 Apr 2021 10:21:29 |
| User signature succeeded.  | Murray Kimmel (b) (4)   | 30 Mar 2021 18:10:57 |
| User entered '29 Jan 2021' | Taylor Atkinson (b) (4) | 22 Feb 2021 22:49:20 |

**US3902021**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 10:17:24**

[Please select one status for the follow-up contact](#)

| Audit                                      | User                    | Time (GMT)           |
|--|-------------------------|----------------------|
| Data hard locked.                          | (b) (4), (b) (6)        | 27 Apr 2021 10:21:29 |
| User signature succeeded.                  | Murray Kimmel (b) (4)   | 30 Mar 2021 18:10:57 |
| User entered 'Contact Made (CONTACT MADE)' | Taylor Atkinson (b) (4) | 22 Feb 2021 22:49:20 |



US3902021

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:17:24

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 27 Apr 2021 10:21:29 |
| User signature succeeded. | Murray Kimmel (b) (4)   | 30 Mar 2021 18:10:57 |
| User entered empty.       | Taylor Atkinson (b) (4) | 22 Feb 2021 22:49:20 |

**US3902021**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 10:17:24**

[Is the participant continuing to the next visit?](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 27 Apr 2021 10:21:29 |
| User signature succeeded. | Murray Kimmel (b) (4)   | 30 Mar 2021 18:10:57 |
| User entered 'Yes (Y)'    | Taylor Atkinson (b) (4) | 22 Feb 2021 22:49:25 |

**US3902021**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 10:17:24**

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 10:21:29 |
| User entered 'I'  | System           | 22 Feb 2021 22:49:25 |

**US3902021**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 10:17:24**

[Was Contact Attempted?](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 27 Apr 2021 10:21:29 |
| User signature succeeded. | Murray Kimmel (b) (4) | 30 Mar 2021 18:10:57 |
| User entered 'Yes (Y)'    | Bram Swarr (b) (4)    | 26 Mar 2021 15:24:33 |

**US3902021**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 10:17:24**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 27 Apr 2021 10:21:29 |
| User signature succeeded.  | Murray Kimmel (b) (4) | 30 Mar 2021 18:10:57 |
| User entered '25 Feb 2021' | Bram Swarr (b) (4)    | 26 Mar 2021 15:24:33 |

**US3902021**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 10:17:24**

[Please select one status for the follow-up contact](#)

| Audit                                      | User                  | Time (GMT)           |
|--|-----------------------|----------------------|
| Data hard locked.                          | (b) (4), (b) (6)      | 27 Apr 2021 10:21:29 |
| User signature succeeded.                  | Murray Kimmel (b) (4) | 30 Mar 2021 18:10:57 |
| User entered 'Contact Made (CONTACT MADE)' | Bram Swarr (b) (4)    | 26 Mar 2021 15:24:33 |

US3902021

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:17:24

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 27 Apr 2021 10:21:29 |
| User signature succeeded. | Murray Kimmel (b) (4) | 30 Mar 2021 18:10:57 |
| User entered empty.       | Bram Swarr (b) (4)    | 26 Mar 2021 15:24:33 |

**US3902021**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 10:17:24**

[Is the participant continuing to the next visit?](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 27 Apr 2021 10:21:29 |
| User signature succeeded. | Murray Kimmel (b) (4) | 30 Mar 2021 18:10:57 |
| User entered 'Yes (Y)'    | Bram Swarr (b) (4)    | 26 Mar 2021 15:24:55 |



**US3902021**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 10:17:24**

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 10:21:29 |
| User entered 'I'  | System           | 26 Mar 2021 15:24:55 |

**US3902021**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 10:17:24**

[Was this visit performed?](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 28 Apr 2021 20:31:25 |
| User signature succeeded. | Murray Kimmel (b) (4) | 30 Mar 2021 18:11:36 |
| User entered 'Yes (Y)'    | Bram Swarr (b) (4)    | 26 Mar 2021 15:29:04 |

**US3902021**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 10:17:24**

[Visit date \(dd MMM yyyy\)](#)

| Audit  | User                  | Time (GMT)           |
|--|-----------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)      | 28 Apr 2021 20:31:25 |
| User signature succeeded.                                      | Murray Kimmel (b) (4) | 30 Mar 2021 18:11:36 |
| User entered '25 Mar 2021' reason for change: Data Entry Error | Bram Swarr (b) (4)    | 26 Mar 2021 15:31:19 |
| User entered '24 Mar 2021'                                     | Bram Swarr (b) (4)    | 26 Mar 2021 15:29:04 |

**US3902021**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 10:17:24**

[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 20:31:25 |
| User signature succeeded.      | Murray Kimmel (b) (4) | 30 Mar 2021 18:11:36 |
| User entered 'Clinic (Clinic)' | Bram Swarr (b) (4)    | 26 Mar 2021 15:29:04 |

**US3902021**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 10:17:24**

[Folder OID](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| Data hard locked.     | (b) (4), (b) (6) | 28 Apr 2021 20:31:25 |
| User entered 'VISIT4' | System           | 26 Mar 2021 15:29:04 |

**US3902021**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 10:17:24**

[Were vital signs assessed?](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 28 Apr 2021 20:31:25 |
| User signature succeeded. | Murray Kimmel (b) (4) | 16 Apr 2021 20:42:13 |
| User entered 'Yes (Y)'    | Bram Swarr (b) (4)    | 30 Mar 2021 19:06:56 |

**US3902021**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 10:17:24**

**Date of assessment (dd MMM yyyy)**

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 28 Apr 2021 20:31:25 |
| User signature succeeded.  | Murray Kimmel (b) (4) | 16 Apr 2021 20:42:13 |
| User entered '25 Mar 2021' | Bram Swarr (b) (4)    | 30 Mar 2021 19:06:56 |

**US3902021**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 10:17:24**

**Time of assessment (00:00-23:59)**

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 28 Apr 2021 20:31:25 |
| User signature succeeded. | Murray Kimmel (b) (4) | 16 Apr 2021 20:42:13 |
| User entered '14:18'      | Bram Swarr (b) (4)    | 30 Mar 2021 19:06:56 |



**US3902021**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 10:17:24**

[Vital Signs Date and Time \(derived\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 28 Apr 2021 20:31:25 |
| User entered '25 Mar 2021 14:18' | System           | 30 Mar 2021 19:06:56 |

**US3902021**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 10:17:24**

[Temperature \(xxx.x\)](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 28 Apr 2021 20:31:25 |
| User signature succeeded. | Murray Kimmel (b) (4) | 16 Apr 2021 20:42:13 |
| User entered '98.8' F     | Bram Swarr (b) (4)    | 30 Mar 2021 19:06:56 |

**US3902021**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 10:17:24**

[Route of measurement](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 28 Apr 2021 20:31:25 |
| User signature succeeded.  | Murray Kimmel (b) (4) | 16 Apr 2021 20:42:13 |
| User entered 'Oral (Oral)' | Bram Swarr (b) (4)    | 30 Mar 2021 19:06:56 |

**US3902021**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 10:17:24**

[If Other, specify](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 28 Apr 2021 20:31:25 |
| User signature succeeded. | Murray Kimmel (b) (4) | 16 Apr 2021 20:42:13 |
| User entered empty.       | Bram Swarr (b) (4)    | 30 Mar 2021 19:06:56 |

**US3902021**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 10:17:24**

[Pulse \(xxx\)](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 28 Apr 2021 20:31:25 |
| User signature succeeded. | Murray Kimmel (b) (4) | 16 Apr 2021 20:42:13 |
| User entered '73'         | Bram Swarr (b) (4)    | 30 Mar 2021 19:06:56 |

**US3902021**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 10:17:24**

[Pulse units](#)

| Audit              | User             | Time (GMT)           |
|--------------------|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 28 Apr 2021 20:31:25 |
| User entered 'bpm' | System           | 30 Mar 2021 19:06:56 |

**US3902021**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 10:17:24**

[Respiratory Rate \(xxx\)](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 28 Apr 2021 20:31:25 |
| User signature succeeded. | Murray Kimmel (b) (4) | 16 Apr 2021 20:42:13 |
| User entered '16'         | Bram Swarr (b) (4)    | 30 Mar 2021 19:06:56 |

**US3902021**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 10:17:24**

[Respiratory Rate units](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6) | 28 Apr 2021 20:31:25 |
| User entered 'breaths/min' | System           | 30 Mar 2021 19:06:56 |



**US3902021**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 10:17:24**

[Systolic Blood Pressure \(xxx\)](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 28 Apr 2021 20:31:25 |
| User signature succeeded. | Murray Kimmel (b) (4) | 16 Apr 2021 20:42:13 |
| User entered '103'        | Bram Swarr (b) (4)    | 30 Mar 2021 19:06:56 |

**US3902021**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 10:17:24**

[Systolic Blood Pressure units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 20:31:25 |
| User entered 'mmHg' | System           | 30 Mar 2021 19:06:56 |

**US3902021**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 10:17:24**

[Diastolic Blood Pressure \(xxx\)](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 28 Apr 2021 20:31:25 |
| User signature succeeded. | Murray Kimmel (b) (4) | 16 Apr 2021 20:42:13 |
| User entered '70'         | Bram Swarr (b) (4)    | 30 Mar 2021 19:06:56 |

**US3902021**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 10:17:24**

[Diastolic Blood Pressure units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 20:31:25 |
| User entered 'mmHg' | System           | 30 Mar 2021 19:06:56 |

**US3902021**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 10:17:24**

[Height \(derived\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:31:25 |
|                   |                  |                      |

**US3902021**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 10:17:24**

[Weight \(derived\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:31:25 |
|                   |                  |                      |

**US3902021**

**Folder: Visit 4 Day 209 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 10:17:24**

[Was the physical examination performed?](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 28 Apr 2021 20:31:25 |
| User signature succeeded. | Murray Kimmel (b) (4) | 30 Mar 2021 18:11:36 |
| User entered 'No (N)'     | Bram Swarr (b) (4)    | 26 Mar 2021 15:29:18 |

US3902021

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:17:24

Date of examination (dd MMM yyyy)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 28 Apr 2021 20:31:25 |
| User signature succeeded. | Murray Kimmel (b) (4) | 30 Mar 2021 18:11:36 |
| User entered empty.       | Bram Swarr (b) (4)    | 26 Mar 2021 15:29:18 |



**US3902021**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 10:17:24**

[Was the sample collected?](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 28 Apr 2021 20:31:25 |
| User signature succeeded. | Murray Kimmel (b) (4) | 30 Mar 2021 18:11:36 |
| User entered 'Yes (Y)'    | Bram Swarr (b) (4)    | 26 Mar 2021 15:30:00 |

US3902021

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:17:24

Collection date (dd MMM yyyy)

| Audit   | User                  | Time (GMT)           |
|---|-----------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)      | 28 Apr 2021 20:31:25 |
| User signature succeeded.   | Murray Kimmel (b) (4) | 30 Mar 2021 18:11:36 |
| User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).                    | System                | 26 Mar 2021 15:31:19 |
| Query 'The Collection Date is not equal to Visit Date. System Please review and reconcile.' answered by data change (Site from System). |                       | 26 Mar 2021 15:31:19 |
| User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).                    | System                | 26 Mar 2021 15:31:11 |
| User entered '25 Mar 2021' reason for change: Data Entry Error  | Bram Swarr (b) (4)    | 26 Mar 2021 15:31:11 |
| User entered '24 Mar 2021'  | Bram Swarr (b) (4)    | 26 Mar 2021 15:30:00 |

**US3902021**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 10:17:24**

[Collection time \(00:00-23:59\)](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 28 Apr 2021 20:31:25 |
| User signature succeeded. | Murray Kimmel (b) (4) | 30 Mar 2021 18:11:36 |
| User entered '14:46'      | Bram Swarr (b) (4)    | 26 Mar 2021 15:30:00 |

**US3902021**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 10:17:24**

[Collection date and time \(derived\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 28 Apr 2021 20:31:25 |
| User entered '25 Mar 2021 14:46' | System           | 26 Mar 2021 15:31:11 |
| User entered '24 Mar 2021 14:46' | System           | 26 Mar 2021 15:30:00 |

**US3902021**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 10:17:24**

[Is the participant continuing to the next visit?](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 28 Apr 2021 20:31:25 |
| User signature succeeded. | Murray Kimmel (b) (4) | 30 Mar 2021 18:11:36 |
| User entered 'Yes (Y)'    | Bram Swarr (b) (4)    | 26 Mar 2021 15:31:26 |

**US3902021**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 10:17:24**

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:31:25 |
| User entered 'I'  | System           | 26 Mar 2021 15:31:26 |

US3902021

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:17:24

[Was this visit performed?](#)

| Audit  | User                    | Time (GMT)           |
|--|-------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)        | 28 Apr 2021 19:41:42 |
| User signature succeeded.  | Murray Kimmel (b) (4)   | 30 Mar 2021 18:10:57 |
| User entered 'Yes (Y)' reason for change: Data Entry Error                             | Taylor Atkinson (b) (4) | 17 Mar 2021 12:19:53 |
| User closed query 'Data is required. Please complete.' (Site from System).             | (b) (4), (b) (6)        | 02 Feb 2021 05:43:31 |
| Query 'Data is required. Please complete.' answered with 'no data' (Site from System). | Bram Swarr (b) (4)      | 01 Feb 2021 18:17:20 |
| User opened query 'Data is required. Please complete.' (Site from System).             | System                  | 01 Feb 2021 18:16:57 |
| User entered empty; reason for change Data Entry Error                                 | Bram Swarr (b) (4)      | 01 Feb 2021 18:16:57 |
| User entered 'Yes (Y)'   | Bram Swarr (b) (4)      | 01 Feb 2021 18:15:51 |

**US3902021**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 10:17:24**

[Visit date \(dd MMM yyyy\)](#)

| Audit  | User                    | Time (GMT)           |
|--|-------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)        | 28 Apr 2021 19:41:42 |
| User signature succeeded.                                      | Murray Kimmel (b) (4)   | 30 Mar 2021 18:10:57 |
| User entered '10 Mar 2021' reason for change: Data Entry Error | Taylor Atkinson (b) (4) | 17 Mar 2021 12:19:53 |
| User entered empty; reason for change Data Entry Error         | Bram Swarr (b) (4)      | 01 Feb 2021 18:16:57 |
| User entered '27 Jan 2021'                                     | Bram Swarr (b) (4)      | 01 Feb 2021 18:15:51 |



**US3902021**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 10:17:24**

[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 19:41:42 |
| User signature succeeded.   | Murray Kimmel (b) (4)   | 30 Mar 2021 18:10:57 |
| User entered 'Clinic (Clinic)' reason for change:<br>Data Entry Error | Taylor Atkinson (b) (4) | 17 Mar 2021 12:19:53 |
| User entered empty; reason for change Data Entry<br>Error             | Bram Swarr (b) (4)      | 01 Feb 2021 18:16:57 |
| User entered 'Clinic (Clinic)'  | Bram Swarr (b) (4)      | 01 Feb 2021 18:15:51 |

**US3902021**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 10:17:24**

[Folder OID](#)

| Audit                        | User             | Time (GMT)           |
|------------------------------|------------------|----------------------|
| Data hard locked.            | (b) (4), (b) (6) | 28 Apr 2021 19:41:42 |
| User entered 'UNBLND_DECIDE' | System           | 17 Mar 2021 12:19:53 |
| User entered empty.          | System           | 01 Feb 2021 18:16:57 |
| User entered 'UNBLND_DECIDE' | System           | 01 Feb 2021 18:15:51 |

**US3902021**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 10:17:24**

[Date of updated informed consent \(dd MMM yyyy\)](#)

| Audit                      | User                    | Time (GMT)           |
|----------------------------|-------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)        | 28 Apr 2021 19:41:42 |
| User signature succeeded.  | Murray Kimmel (b) (4)   | 30 Mar 2021 18:10:57 |
| User entered '10 Mar 2021' | Taylor Atkinson (b) (4) | 17 Mar 2021 12:20:48 |

**US3902021**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 10:17:24**

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 28 Apr 2021 19:41:42 |
| User signature succeeded. | Murray Kimmel (b) (4)   | 30 Mar 2021 18:10:57 |
| User entered '0'          | Taylor Atkinson (b) (4) | 17 Mar 2021 12:20:48 |

**US3902021**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 10:17:24**

[Was the participant unblinded?](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 28 Apr 2021 19:41:42 |
| User signature succeeded. | Murray Kimmel (b) (4)   | 30 Mar 2021 18:10:57 |
| User entered 'Yes (Y)'    | Taylor Atkinson (b) (4) | 17 Mar 2021 12:20:48 |

**US3902021**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 10:17:24**

[Under what version of the Protocol was the Participant unblinded?](#)

| Audit  | User                    | Time (GMT)           |
|--|-------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)        | 28 Apr 2021 19:41:42 |
| User signature succeeded.                                  | Murray Kimmel (b) (4)   | 30 Mar 2021 18:10:57 |
| User entered 'Amendment 6 or later (Amendment 6 or later)' | Taylor Atkinson (b) (4) | 17 Mar 2021 12:20:48 |

**US3902021**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 10:17:24**

**Date of unblinding** (*dd MMM yyyy*)

| Audit                      | User                    | Time (GMT)           |
|----------------------------|-------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)        | 28 Apr 2021 19:41:42 |
| User signature succeeded.  | Murray Kimmel (b) (4)   | 30 Mar 2021 18:10:57 |
| User entered '10 Mar 2021' | Taylor Atkinson (b) (4) | 17 Mar 2021 12:20:48 |

**US3902021**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 10:17:24**

[Participant randomization assignment](#)

| Audit                                | User                    | Time (GMT)           |
|--------------------------------------|-------------------------|----------------------|
| Data hard locked.                    | (b) (4), (b) (6)        | 28 Apr 2021 19:41:42 |
| User signature succeeded.            | Murray Kimmel (b) (4)   | 30 Mar 2021 18:10:57 |
| User entered 'mRNA-1273 (mRNA-1273)' | Taylor Atkinson (b) (4) | 17 Mar 2021 12:20:48 |



**US3902021**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 10:17:24**

[Actual Dose 1](#)

| Audit                                | User                    | Time (GMT)           |
|--------------------------------------|-------------------------|----------------------|
| Data hard locked.                    | (b) (4), (b) (6)        | 28 Apr 2021 19:41:42 |
| User signature succeeded.            | Murray Kimmel (b) (4)   | 30 Mar 2021 18:10:57 |
| User entered 'mRNA-1273 (mRNA-1273)' | Taylor Atkinson (b) (4) | 17 Mar 2021 12:20:48 |

**US3902021**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 10:17:24**

[Actual Dose 2](#)

| Audit                                | User                    | Time (GMT)           |
|--------------------------------------|-------------------------|----------------------|
| Data hard locked.                    | (b) (4), (b) (6)        | 28 Apr 2021 19:41:42 |
| User signature succeeded.            | Murray Kimmel (b) (4)   | 30 Mar 2021 18:10:57 |
| User entered 'mRNA-1273 (mRNA-1273)' | Taylor Atkinson (b) (4) | 17 Mar 2021 12:20:48 |

**US3902021**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 10:17:24**

[Will participant receive mRNA-1273?](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 28 Apr 2021 19:41:42 |
| User signature succeeded. | Murray Kimmel (b) (4)   | 30 Mar 2021 18:10:57 |
| User entered 'No (N)'     | Taylor Atkinson (b) (4) | 17 Mar 2021 12:20:48 |

**US3902021**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 10:17:24**

[Placebo Only Flag](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 19:41:42 |
| User entered empty. | System           | 17 Mar 2021 12:20:48 |

**US3902021**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 10:17:24**

[Continuing with mRNA-1273](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 19:41:42 |
| User entered empty. | System           | 17 Mar 2021 12:20:48 |

**US3902021**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 10:17:24**

[Was the sample collected?](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 28 Apr 2021 19:41:42 |
| User signature succeeded. | Murray Kimmel (b) (4)   | 16 Apr 2021 20:42:13 |
| User entered 'Yes (Y)'    | Taylor Atkinson (b) (4) | 17 Mar 2021 12:21:25 |

US3902021

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:17:24

Collection date (dd MMM yyyy)

| Audit   | User                    | Time (GMT)           |
|---|-------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)        | 28 Apr 2021 19:41:42 |
| User signature succeeded.   | Murray Kimmel (b) (4)   | 16 Apr 2021 20:42:13 |
| User closed query 'Per Lab Recon:OL-D1 Immuno: Sample dated 10 MAR 2021, is still missing in PPD GCL records. Please confirm if the sample has been collected & shipped, if yes please kindly provide the Accession number, Tracking number, shipping date in response, as this helps to track the missing sample with the details provided. Thank you.' (Site from DM).                              | (b) (4), (b) (6)        | 04 Apr 2021 15:02:14 |
| Query 'Per Lab Recon:OL-D1 Immuno: Sample dated 10 MAR 2021, is still missing in PPD GCL records. Please confirm if the sample has been collected & shipped, if yes please kindly provide the Accession number, Tracking number, shipping date in response, as this helps to track the missing sample with the details provided. Thank you.' answered with 'Sample shipped 30Mar2021' (Site from DM). | Taylor Atkinson (b) (4) | 31 Mar 2021 13:04:52 |
| User opened query 'Per Lab Recon:OL-D1 Immuno: Sample dated 10 MAR 2021, is still missing in PPD GCL records. Please confirm if the sample has been collected & shipped, if yes please kindly provide the Accession number, Tracking number, shipping date in response, as this helps to track the missing sample with the details provided. Thank you.' (Site from DM).                              | (b) (4), (b) (6)        | 26 Mar 2021 11:14:47 |
| User entered '10 Mar 2021'  | Taylor Atkinson (b) (4) | 17 Mar 2021 12:21:25 |

**US3902021**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 10:17:24**

[Collection time \(00:00-23:59\)](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 28 Apr 2021 19:41:42 |
| User signature succeeded. | Murray Kimmel (b) (4)   | 16 Apr 2021 20:42:13 |
| User entered '12:42'      | Taylor Atkinson (b) (4) | 17 Mar 2021 12:21:25 |



**US3902021**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 10:17:24**

[Collection date and time \(derived\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 28 Apr 2021 19:41:42 |
| User entered '10 Mar 2021 12:42' | System           | 17 Mar 2021 12:21:25 |

**US3902021**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 10 Jun 2021 10:17:24**

[Was the sample collected?](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 28 Apr 2021 19:41:42 |
| User signature succeeded. | Murray Kimmel (b) (4)   | 30 Mar 2021 18:10:57 |
| User entered 'Yes (Y)'    | Taylor Atkinson (b) (4) | 17 Mar 2021 12:21:43 |

**US3902021**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 10 Jun 2021 10:17:24**

**Collection date** (*dd MMM yyyy*)

| Audit                      | User                    | Time (GMT)           |
|----------------------------|-------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)        | 28 Apr 2021 19:41:42 |
| User signature succeeded.  | Murray Kimmel (b) (4)   | 30 Mar 2021 18:10:57 |
| User entered '10 Mar 2021' | Taylor Atkinson (b) (4) | 17 Mar 2021 12:21:43 |

**US3902021**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 10 Jun 2021 10:17:24**

[Collection time \(00:00 - 23:59\)](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 28 Apr 2021 19:41:42 |
| User signature succeeded. | Murray Kimmel (b) (4)   | 30 Mar 2021 18:10:57 |
| User entered '12:43'      | Taylor Atkinson (b) (4) | 17 Mar 2021 12:21:43 |

**US3902021**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 10 Jun 2021 10:17:24**

[Collection Date and Time \(derived\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 28 Apr 2021 19:41:42 |
| User entered '10 Mar 2021 12:43' | System           | 17 Mar 2021 12:21:43 |

US3902021

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 10:17:24

[Did the participant experience any adverse events?](#)

| Audit  | User                    | Time (GMT)           |
|--|-------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)        | 04 May 2021 04:38:00 |
| User signature succeeded.  | Murray Kimmel (b) (4)   | 23 Apr 2021 17:08:48 |
| User closed query 'Per CDM: Per protocol any Solicited local or systemic AR lasting beyond 7 days post-injection must be entered into the participant's source document and must also be recorded as an AE in the participant's Adverse Event eCRF. Per subject's diary 1 Joint Aches, and diary 2 Headache both lasted beyond day 7 post injection. Please reconcile and enter evens as needed per Completion Guidelines (page 47/48) and ensure SAR box is checked.' (Site from DM).             | (b) (4), (b) (6)        | 20 Apr 2021 07:54:26 |
| Query 'Per CDM: Per protocol any Solicited local or systemic AR lasting beyond 7 days post-injection must be entered into the participant's source document and must also be recorded as an AE in the participant's Adverse Event eCRF. Per subject's diary 1 Joint Aches, and diary 2 Headache both lasted beyond day 7 post injection. Please reconcile and enter evens as needed per Completion Guidelines (page 47/48) and ensure SAR box is checked.' answered with 'updated' (Site from DM). | Taylor Atkinson (b) (4) | 19 Apr 2021 19:24:15 |
| User opened query 'Per CDM: Per protocol any Solicited local or systemic AR lasting beyond 7 days post-injection must be entered into the participant's source document and must also be recorded as an AE in the participant's Adverse Event eCRF. Per subject's diary 1 Joint Aches, and diary 2 Headache both lasted beyond day 7 post injection. Please reconcile and enter evens as needed per Completion Guidelines (page 47/48) and ensure SAR box is checked.' (Site from DM).             | (b) (4), (b) (6)        | 16 Apr 2021 15:33:35 |

US3902021

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 10:17:24

[Did the participant experience any adverse events?](#)

| Audit  | User                    | Time (GMT)           |
|--|-------------------------|----------------------|
| User closed query 'Per DM CLR: As per Safety Follow-up Diary entry in Day 173, Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' (Site from DM).                | (b) (4), (b) (6)        | 06 Apr 2021 07:44:21 |
| Query 'Per DM CLR: As per Safety Follow-up Diary entry in Day 173, Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' answered with 'SAE logged' (Site from DM). | Taylor Atkinson (b) (4) | 05 Apr 2021 20:09:48 |
| User opened query 'Per DM CLR: As per Safety Follow-up Diary entry in Day 173, Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' (Site from DM).                | (b) (4), (b) (6)        | 27 Mar 2021 03:19:19 |
| User entered 'Yes (Y)'   | Katrina Carlson (b) (4) | 02 Mar 2021 00:37:16 |

**US3902021**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 10:17:24**

[AEID](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Reviewed for Safety.                                  | (b) (4), (b) (6) | 02 Mar 2021 15:39:06 |
| User entered<br>'USA-US210-2021-mRNA-1273-P301000002' | System           | 02 Mar 2021 15:38:31 |
| User entered 'New'                                    | (b) (4), (b) (6) | 02 Mar 2021 15:38:31 |



US3902021

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:17:24

[Adverse event](#)

| Audit  | User                    | Time (GMT)           |
|--|-------------------------|----------------------|
| User coded data point as SOC: Hepatobiliary disorders, HLGT: Gallbladder disorders, HLT: Cholecystitis and cholelithiasis, PT: Cholelithiasis, LLT: Cholelithiasis - version MedDRA\\23.0. | Coder Import (b) (4)    | 02 Mar 2021 00:55:01 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.   | Coder Import (b) (4)    | 02 Mar 2021 00:55:01 |
| Data point term sent to Coder  | System                  | 02 Mar 2021 00:54:11 |
| User entered 'cholelithiasis'  | Katrina Carlson (b) (4) | 02 Mar 2021 00:53:52 |
|  | (b) (4)                 |                      |

**US3902021**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 10:17:24**

[Was this a medically-attended AE?](#)

| Audit                  | User                               | Time (GMT)           |
|------------------------|------------------------------------|----------------------|
| User entered 'Yes (Y)' | Katrina Carlson (b) (4)<br>(b) (4) | 02 Mar 2021 00:53:52 |

**US3902021**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 10:17:24**

[Was this a Solicited Adverse Reaction?](#)

| Audit                 | User                               | Time (GMT)           |
|-----------------------|------------------------------------|----------------------|
| User entered 'No (N)' | Katrina Carlson (b) (4)<br>(b) (4) | 02 Mar 2021 00:53:52 |

**US3902021**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 10:17:24**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit                 | User                               | Time (GMT)           |
|-----------------------|------------------------------------|----------------------|
| User entered 'No (N)' | Katrina Carlson (b) (4)<br>(b) (4) | 02 Mar 2021 00:53:52 |

**US3902021**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 10:17:24**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                               | Time (GMT)           |
|----------------------------|------------------------------------|----------------------|
| User entered '22 Feb 2021' | Katrina Carlson (b) (4)<br>(b) (4) | 02 Mar 2021 00:53:52 |

**US3902021**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 10:17:24**

[Start time \(00:00-23:59\)](#)

| Audit               | User                               | Time (GMT)           |
|---------------------|------------------------------------|----------------------|
| User entered empty. | Katrina Carlson (b) (4)<br>(b) (4) | 02 Mar 2021 00:53:52 |

**US3902021**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 10:17:24**

[AE start date and time \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 02 Mar 2021 00:53:52 |

**US3902021**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 10:17:24**

[Ongoing?](#)

| Audit   | User                    | Time (GMT)           |
|---|-------------------------|----------------------|
| User entered 'No (N)' reason for change: Data Entry Error | Taylor Atkinson (b) (4) | 17 Mar 2021 12:24:17 |
| User entered 'Yes (Y)'                                    | Katrina Carlson (b) (4) | 02 Mar 2021 00:53:52 |



**US3902021**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 10:17:24**

*If not Ongoing, end date (dd MMM yyyy)*

| Audit   | User                    | Time (GMT)           |
|---|-------------------------|----------------------|
| User entered '1 Mar 2021' reason for change: Data Entry Error | Taylor Atkinson (b) (4) | 17 Mar 2021 12:24:17 |
| User entered empty.   | Katrina Carlson (b) (4) | 02 Mar 2021 00:53:52 |

**US3902021**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 10:17:24**

[End time \(00:00-23:59\)](#)

| Audit               | User                               | Time (GMT)           |
|---------------------|------------------------------------|----------------------|
| User entered empty. | Katrina Carlson (b) (4)<br>(b) (4) | 02 Mar 2021 00:53:52 |

**US3902021**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 10:17:24**

[AE End Date and Time \(derived\)](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Query 'PV Query: Please provide the event end date, when available. Please leave query open until information is available.' canceled (Site from Safety).    | (b) (4), (b) (6) | 23 Mar 2021 19:18:16 |
| User opened query 'PV Query: Please provide the event end date, when available. Please leave query open until information is available.' (Site from Safety). | (b) (4), (b) (6) | 10 Mar 2021 16:08:16 |
| User entered empty.  | System           | 02 Mar 2021 00:53:52 |

**US3902021**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 10:17:24**

[Severity](#)

| Audit  | User                               | Time (GMT)           |
|--|------------------------------------|----------------------|
| User entered 'Grade 3/Severe (Grade 3/Severe)' | Katrina Carlson (b) (4)<br>(b) (4) | 02 Mar 2021 00:53:52 |

**US3902021**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 10:17:24**

[Is the adverse event serious?](#)

| Audit                  | User                               | Time (GMT)           |
|------------------------|------------------------------------|----------------------|
| User entered 'Yes (Y)' | Katrina Carlson (b) (4)<br>(b) (4) | 02 Mar 2021 00:53:52 |

**US3902021**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 10:17:24**

[Death](#)

| Audit            | User                               | Time (GMT)           |
|------------------|------------------------------------|----------------------|
| User entered '0' | Katrina Carlson (b) (4)<br>(b) (4) | 02 Mar 2021 00:53:52 |

**US3902021**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 10:17:24**

[Life threatening](#)

| Audit            | User                               | Time (GMT)           |
|------------------|------------------------------------|----------------------|
| User entered '0' | Katrina Carlson (b) (4)<br>(b) (4) | 02 Mar 2021 00:53:52 |

**US3902021**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 10:17:24**

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit            | User                               | Time (GMT)           |
|------------------|------------------------------------|----------------------|
| User entered 'I' | Katrina Carlson (b) (4)<br>(b) (4) | 02 Mar 2021 00:53:52 |



US3902021

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:17:24

Hospital Admission Date (*dd MMM yyyy*)

| Audit                      | User                               | Time (GMT)           |
|----------------------------|------------------------------------|----------------------|
| User entered '22 Feb 2021' | Katrina Carlson (b) (4)<br>(b) (4) | 02 Mar 2021 00:53:52 |

**US3902021**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 10:17:24**

**Hospital Discharge Date (*dd MMM yyyy*)**

| Audit                      | User                               | Time (GMT)           |
|----------------------------|------------------------------------|----------------------|
| User entered '25 Feb 2021' | Katrina Carlson (b) (4)<br>(b) (4) | 02 Mar 2021 00:53:52 |

**US3902021**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 10:17:24**

[Admitted to ICU?](#)

| Audit                 | User                               | Time (GMT)           |
|-----------------------|------------------------------------|----------------------|
| User entered 'No (N)' | Katrina Carlson (b) (4)<br>(b) (4) | 02 Mar 2021 00:53:52 |

**US3902021**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 10:17:24**

[Number of Days in ICU](#)

| Audit               | User                               | Time (GMT)           |
|---------------------|------------------------------------|----------------------|
| User entered empty. | Katrina Carlson (b) (4)<br>(b) (4) | 02 Mar 2021 00:53:52 |

US3902021

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:17:24

Persistent or significant disability or incapacity

| Audit            | User                               | Time (GMT)           |
|------------------|------------------------------------|----------------------|
| User entered '0' | Katrina Carlson (b) (4)<br>(b) (4) | 02 Mar 2021 00:53:52 |

**US3902021**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 10:17:24**

[Congenital anomaly or birth defect](#)

| Audit            | User                               | Time (GMT)           |
|------------------|------------------------------------|----------------------|
| User entered '0' | Katrina Carlson (b) (4)<br>(b) (4) | 02 Mar 2021 00:53:52 |

**US3902021**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 10:17:24**

[Other medically important event](#)

| Audit            | User                               | Time (GMT)           |
|------------------|------------------------------------|----------------------|
| User entered '0' | Katrina Carlson (b) (4)<br>(b) (4) | 02 Mar 2021 00:53:52 |

**US3902021**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 10:17:24**

[Relationship to investigational product](#)

| Audit                                    | User                               | Time (GMT)           |
|--|------------------------------------|----------------------|
| User entered 'Not Related (NOT RELATED)' | Katrina Carlson (b) (4)<br>(b) (4) | 02 Mar 2021 00:53:52 |



**US3902021**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 10:17:24**

[Relationship to Study Procedure](#)

| Audit                                    | User                               | Time (GMT)           |
|--|------------------------------------|----------------------|
| User entered 'Not Related (NOT RELATED)' | Katrina Carlson (b) (4)<br>(b) (4) | 02 Mar 2021 00:53:52 |

**US3902021**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 10:17:24**

[Action taken with investigational product](#)

| Audit  | User                               | Time (GMT)           |
|--|------------------------------------|----------------------|
| User entered 'Not Applicable (NOT APPLICABLE)' | Katrina Carlson (b) (4)<br>(b) (4) | 02 Mar 2021 00:53:52 |

**US3902021**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 10:17:24**

[None](#)

| Audit            | User                               | Time (GMT)           |
|------------------|------------------------------------|----------------------|
| User entered '0' | Katrina Carlson (b) (4)<br>(b) (4) | 02 Mar 2021 00:53:52 |

US3902021

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:17:24

[Concomitant Medication](#)

| Audit   | User                               | Time (GMT)           |
|---|------------------------------------|----------------------|
| User closed query 'PV Query: Please add concomitant medication received within 30 days prior to event (or >30 days if relevant to event) to concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If none, please state so.' (Site from Safety).                                 | (b) (4), (b) (6)                   | 29 Mar 2021 15:09:57 |
| Query 'PV Query: Please add concomitant medication received within 30 days prior to event (or >30 days if relevant to event) to concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If none, please state so.' answered with 'these were already entered.' (Site from Safety). | Bram Swarr (b) (4)                 | 26 Mar 2021 15:27:35 |
| User opened query 'PV Query: Please add concomitant medication received within 30 days prior to event (or >30 days if relevant to event) to concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If none, please state so.' (Site from Safety).                                 | (b) (4), (b) (6)                   | 10 Mar 2021 16:05:58 |
| User entered 'I'  | Katrina Carlson (b) (4)<br>(b) (4) | 02 Mar 2021 00:53:52 |

**US3902021**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 10:17:24**

[Concomitant Procedure](#)

| Audit            | User                               | Time (GMT)           |
|------------------|------------------------------------|----------------------|
| User entered 'I' | Katrina Carlson (b) (4)<br>(b) (4) | 02 Mar 2021 00:53:52 |

US3902021

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:17:24

[Outcome](#)

| Audit  | User                    | Time (GMT)           |
|--|-------------------------|----------------------|
| User closed query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety).             | (b) (4), (b) (6)        | 18 Mar 2021 16:39:35 |
| Query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' answered with 'updated' (Site from Safety). | Taylor Atkinson (b) (4) | 17 Mar 2021 12:24:25 |
| User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error   | Taylor Atkinson (b) (4) | 17 Mar 2021 12:24:17 |
| User opened query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety).             | (b) (4), (b) (6)        | 10 Mar 2021 16:07:47 |
| User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'   | Katrina Carlson (b) (4) | 02 Mar 2021 00:53:52 |

**US3902021**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 10:17:24**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

| Audit               | User                               | Time (GMT)           |
|---------------------|------------------------------------|----------------------|
| User entered empty. | Katrina Carlson (b) (4)<br>(b) (4) | 02 Mar 2021 00:53:52 |

US3902021

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:17:24

[Narrative](#)

| Audit  | User                               | Time (GMT)           |
|--|------------------------------------|----------------------|
| Query 'PV Query: Please add subject's medical history (prior to onset of study) to medical history eCRF. If none, please state so.' canceled (Site from Safety).   | (b) (4), (b) (6)                   | 23 Mar 2021 16:39:14 |
| User opened query 'PV Query: Please add subject's medical history (prior to onset of study) to medical history eCRF. If none, please state so.' (Site from Safety).  | (b) (4), (b) (6)                   | 10 Mar 2021 16:07:12 |
| User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety). | (b) (4), (b) (6)                   | 10 Mar 2021 16:06:16 |
| 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)                   | 10 Mar 2021 16:06:02 |
| User entered 'Per CRC source notes: During day 179 safety phone contact subject stated she went to Holmes Reginal ER with right side shoulder and belly pain; diagnosed with cholelithiasis on 02/22/2021. A cholecystectomy was performed on 02/23/2021. Subject discharged on 02/25/2021 with a pain med and an antibiotic. Subject states she is feeling better.'                   | Katrina Carlson (b) (4)<br>(b) (4) | 02 Mar 2021 00:53:52 |



**US3902021**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 10:17:24**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 02 Mar 2021 00:53:52 |

**US3902021**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 10:17:24**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered 'I' | System | 02 Mar 2021 00:53:52 |

**US3902021**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 10:17:24**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '0' | System | 02 Mar 2021 00:53:52 |

**US3902021**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 10:17:24**

[AEID](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 16:09:27 |
|                   |                  |                      |

US3902021

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:17:24

[Adverse event](#)

| Audit  | User                               | Time (GMT)           |
|--|------------------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)                   | 30 Apr 2021 16:09:27 |
| User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related signs and symptoms, PT: Arthralgia, LLT: Arthralgia - version MedDRA\\23.0. | Coder Import (b) (4)<br>(b) (4)    | 19 Apr 2021 19:29:47 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.   | Coder Import (b) (4)<br>(b) (4)    | 19 Apr 2021 19:29:47 |
| Data point term sent to Coder  | System                             | 19 Apr 2021 19:29:02 |
| User entered 'Arthralgia'  | Taylor Atkinson (b) (4)<br>(b) (4) | 19 Apr 2021 19:28:24 |

**US3902021**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 10:17:24**

[Was this a medically-attended AE?](#)

| Audit                 | User                    | Time (GMT)           |
|-----------------------|-------------------------|----------------------|
| Data hard locked.     | (b) (4), (b) (6)        | 30 Apr 2021 16:09:27 |
| User entered 'No (N)' | Taylor Atkinson (b) (4) | 19 Apr 2021 19:28:24 |

**US3902021**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 10:17:24**

[Was this a Solicited Adverse Reaction?](#)

| Audit                  | User                    | Time (GMT)           |
|------------------------|-------------------------|----------------------|
| Data hard locked.      | (b) (4), (b) (6)        | 30 Apr 2021 16:09:27 |
| User entered 'Yes (Y)' | Taylor Atkinson (b) (4) | 19 Apr 2021 19:28:24 |

**US3902021**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 10:17:24**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit                 | User                               | Time (GMT)           |
|-----------------------|------------------------------------|----------------------|
| Data hard locked.     | (b) (4), (b) (6)                   | 30 Apr 2021 16:09:27 |
| User entered 'No (N)' | Taylor Atkinson (b) (4)<br>(b) (4) | 19 Apr 2021 19:28:24 |



**US3902021**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 10:17:24**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                    | Time (GMT)           |
|----------------------------|-------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)        | 30 Apr 2021 16:09:27 |
| User entered '11 Sep 2020' | Taylor Atkinson (b) (4) | 19 Apr 2021 19:28:24 |
|                            | (b) (4)                 |                      |

**US3902021**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 10:17:24**

[Start time \(00:00-23:59\)](#)

| Audit               | User                    | Time (GMT)           |
|---------------------|-------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)        | 30 Apr 2021 16:09:27 |
| User entered empty. | Taylor Atkinson (b) (4) | 19 Apr 2021 19:28:24 |

**US3902021**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 10:17:24**

[AE start date and time \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 30 Apr 2021 16:09:27 |
| User entered empty. | System           | 19 Apr 2021 19:28:24 |

**US3902021**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 10:17:24**

[Ongoing?](#)

| Audit                 | User                    | Time (GMT)           |
|-----------------------|-------------------------|----------------------|
| Data hard locked.     | (b) (4), (b) (6)        | 30 Apr 2021 16:09:27 |
| User entered 'No (N)' | Taylor Atkinson (b) (4) | 19 Apr 2021 19:28:24 |

**US3902021**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 10:17:24**

*If not Ongoing, end date (dd MMM yyyy)*

| Audit                      | User                    | Time (GMT)           |
|----------------------------|-------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)        | 30 Apr 2021 16:09:27 |
| User entered '11 Sep 2020' | Taylor Atkinson (b) (4) | 19 Apr 2021 19:28:24 |

**US3902021**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 10:17:24**

[End time \(00:00-23:59\)](#)

| Audit               | User                    | Time (GMT)           |
|---------------------|-------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)        | 30 Apr 2021 16:09:27 |
| User entered empty. | Taylor Atkinson (b) (4) | 19 Apr 2021 19:28:24 |

**US3902021**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 10:17:24**

[AE End Date and Time \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 30 Apr 2021 16:09:27 |
| User entered empty. | System           | 19 Apr 2021 19:28:24 |

US3902021

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:17:24

[Severity](#)

| Audit  | User                    | Time (GMT)           |
|--|-------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)        | 30 Apr 2021 16:09:27 |
| User closed query 'Data is required. Please complete.' (Site from System).             | System                  | 19 Apr 2021 19:29:50 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System                  | 19 Apr 2021 19:29:50 |
| User entered 'Grade 1/Mild (Grade 1/Mild)' reason for change: Data Entry Error         | Taylor Atkinson (b) (4) | 19 Apr 2021 19:29:50 |
| User opened query 'Data is required. Please complete.' (Site from System).             | System                  | 19 Apr 2021 19:28:24 |
| User entered empty.  | Taylor Atkinson (b) (4) | 19 Apr 2021 19:28:24 |



**US3902021**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 10:17:24**

[Is the adverse event serious?](#)

| Audit                 | User                    | Time (GMT)           |
|-----------------------|-------------------------|----------------------|
| Data hard locked.     | (b) (4), (b) (6)        | 30 Apr 2021 16:09:27 |
| User entered 'No (N)' | Taylor Atkinson (b) (4) | 19 Apr 2021 19:28:24 |

**US3902021**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 10:17:24**

[Death](#)

| Audit             | User                    | Time (GMT)           |
|-------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6)        | 30 Apr 2021 16:09:27 |
| User entered '0'  | Taylor Atkinson (b) (4) | 19 Apr 2021 19:28:24 |

**US3902021**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 10:17:24**

[Life threatening](#)

| Audit             | User                    | Time (GMT)           |
|-------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6)        | 30 Apr 2021 16:09:27 |
| User entered '0'  | Taylor Atkinson (b) (4) | 19 Apr 2021 19:28:24 |

**US3902021**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 10:17:24**

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit             | User                    | Time (GMT)           |
|-------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6)        | 30 Apr 2021 16:09:27 |
| User entered '0'  | Taylor Atkinson (b) (4) | 19 Apr 2021 19:28:24 |

**US3902021**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 10:17:24**

[Hospital Admission Date \(dd MMM yyyy\)](#)

| Audit               | User                    | Time (GMT)           |
|---------------------|-------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)        | 30 Apr 2021 16:09:27 |
| User entered empty. | Taylor Atkinson (b) (4) | 19 Apr 2021 19:28:24 |

**US3902021**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 10:17:24**

[Hospital Discharge Date \(dd MMM yyyy\)](#)

| Audit               | User                    | Time (GMT)           |
|---------------------|-------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)        | 30 Apr 2021 16:09:27 |
| User entered empty. | Taylor Atkinson (b) (4) | 19 Apr 2021 19:28:24 |

**US3902021**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 10:17:24**

[Admitted to ICU?](#)

| Audit               | User                    | Time (GMT)           |
|---------------------|-------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)        | 30 Apr 2021 16:09:27 |
| User entered empty. | Taylor Atkinson (b) (4) | 19 Apr 2021 19:28:24 |

**US3902021**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 10:17:24**

[Number of Days in ICU](#)

| Audit               | User                    | Time (GMT)           |
|---------------------|-------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)        | 30 Apr 2021 16:09:27 |
| User entered empty. | Taylor Atkinson (b) (4) | 19 Apr 2021 19:28:24 |



**US3902021**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 10:17:24**

[Persistent or significant disability or incapacity](#)

| Audit             | User                    | Time (GMT)           |
|-------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6)        | 30 Apr 2021 16:09:27 |
| User entered '0'  | Taylor Atkinson (b) (4) | 19 Apr 2021 19:28:24 |

**US3902021**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 10:17:24**

[Congenital anomaly or birth defect](#)

| Audit             | User                    | Time (GMT)           |
|-------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6)        | 30 Apr 2021 16:09:27 |
| User entered '0'  | Taylor Atkinson (b) (4) | 19 Apr 2021 19:28:24 |

**US3902021**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 10:17:24**

[Other medically important event](#)

| Audit             | User                    | Time (GMT)           |
|-------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6)        | 30 Apr 2021 16:09:27 |
| User entered '0'  | Taylor Atkinson (b) (4) | 19 Apr 2021 19:28:24 |

**US3902021**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 10:17:24**

[Relationship to investigational product](#)

| Audit                            | User                               | Time (GMT)           |
|----------------------------------|------------------------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6)                   | 30 Apr 2021 16:09:27 |
| User entered 'Related (RELATED)' | Taylor Atkinson (b) (4)<br>(b) (4) | 19 Apr 2021 19:28:24 |

**US3902021**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 10:17:24**

[Relationship to Study Procedure](#)

| Audit                                    | User                               | Time (GMT)           |
|--|------------------------------------|----------------------|
| Data hard locked.                        | (b) (4), (b) (6)                   | 30 Apr 2021 16:09:27 |
| User entered 'Not Related (NOT RELATED)' | Taylor Atkinson (b) (4)<br>(b) (4) | 19 Apr 2021 19:28:24 |

**US3902021**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 10:17:24**

[Action taken with investigational product](#)

| Audit                      | User                    | Time (GMT)           |
|----------------------------|-------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)        | 30 Apr 2021 16:09:27 |
| User entered 'None (NONE)' | Taylor Atkinson (b) (4) | 19 Apr 2021 19:28:24 |

**US3902021**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 10:17:24**

[None](#)

| Audit             | User                    | Time (GMT)           |
|-------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6)        | 30 Apr 2021 16:09:27 |
| User entered '1'  | Taylor Atkinson (b) (4) | 19 Apr 2021 19:28:24 |

**US3902021**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 10:17:24**

[Concomitant Medication](#)

| Audit             | User                               | Time (GMT)           |
|-------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6)                   | 30 Apr 2021 16:09:27 |
| User entered '0'  | Taylor Atkinson (b) (4)<br>(b) (4) | 19 Apr 2021 19:28:24 |



**US3902021**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 10:17:24**

[Concomitant Procedure](#)

| Audit             | User                    | Time (GMT)           |
|-------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6)        | 30 Apr 2021 16:09:27 |
| User entered '0'  | Taylor Atkinson (b) (4) | 19 Apr 2021 19:28:24 |

**US3902021**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 10:17:24**

[Outcome](#)

| Audit  | User                               | Time (GMT)           |
|--|------------------------------------|----------------------|
| Data hard locked.                                      | (b) (4), (b) (6)                   | 30 Apr 2021 16:09:27 |
| User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' | Taylor Atkinson (b) (4)<br>(b) (4) | 19 Apr 2021 19:28:24 |

**US3902021**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 10:17:24**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

| Audit               | User                    | Time (GMT)           |
|---------------------|-------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)        | 30 Apr 2021 16:09:27 |
| User entered empty. | Taylor Atkinson (b) (4) | 19 Apr 2021 19:28:24 |
|                     | (b) (4)                 |                      |

**US3902021**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 10:17:24**

[Narrative](#)

| Audit               | User                               | Time (GMT)           |
|---------------------|------------------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)                   | 30 Apr 2021 16:09:27 |
| User entered empty. | Taylor Atkinson (b) (4)<br>(b) (4) | 19 Apr 2021 19:28:24 |

**US3902021**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 10:17:24**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 16:09:27 |
| User entered '0'  | System           | 19 Apr 2021 19:28:24 |

**US3902021**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 10:17:24**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 16:09:27 |
| User entered '0'  | System           | 19 Apr 2021 19:28:24 |

**US3902021**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 10:17:24**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 16:09:27 |

**US3902021**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 10:17:24**

[AEID](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 16:09:19 |
|                   |                  |                      |



US3902021

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:17:24

[Adverse event](#)

| Audit  | User                               | Time (GMT)           |
|--|------------------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)                   | 30 Apr 2021 16:09:19 |
| User coded data point as SOC: Nervous system disorders, HLGT: Headaches, HLT: Headaches NEC, PT: Headache, LLT: Headache - version MedDRA\\23.0. | Coder Import (b) (4)<br>(b) (4)    | 20 Apr 2021 00:36:50 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.  | Coder Import (b) (4)<br>(b) (4)    | 20 Apr 2021 00:36:50 |
| Data point term sent to Coder  | System                             | 19 Apr 2021 19:30:04 |
| User entered 'Ongoing Headache'  | Taylor Atkinson (b) (4)<br>(b) (4) | 19 Apr 2021 19:29:17 |

**US3902021**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 10:17:24**

[Was this a medically-attended AE?](#)

| Audit                 | User                    | Time (GMT)           |
|-----------------------|-------------------------|----------------------|
| Data hard locked.     | (b) (4), (b) (6)        | 30 Apr 2021 16:09:19 |
| User entered 'No (N)' | Taylor Atkinson (b) (4) | 19 Apr 2021 19:29:17 |

**US3902021**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 10:17:24**

[Was this a Solicited Adverse Reaction?](#)

| Audit                  | User                    | Time (GMT)           |
|------------------------|-------------------------|----------------------|
| Data hard locked.      | (b) (4), (b) (6)        | 30 Apr 2021 16:09:19 |
| User entered 'Yes (Y)' | Taylor Atkinson (b) (4) | 19 Apr 2021 19:29:17 |

**US3902021**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 10:17:24**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit                 | User                               | Time (GMT)           |
|-----------------------|------------------------------------|----------------------|
| Data hard locked.     | (b) (4), (b) (6)                   | 30 Apr 2021 16:09:19 |
| User entered 'No (N)' | Taylor Atkinson (b) (4)<br>(b) (4) | 19 Apr 2021 19:29:17 |

**US3902021**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 10:17:24**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                               | Time (GMT)           |
|----------------------------|------------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                   | 30 Apr 2021 16:09:19 |
| User entered '07 Oct 2020' | Taylor Atkinson (b) (4)<br>(b) (4) | 19 Apr 2021 19:29:17 |

**US3902021**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 10:17:24**

[Start time \(00:00-23:59\)](#)

| Audit               | User                    | Time (GMT)           |
|---------------------|-------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)        | 30 Apr 2021 16:09:19 |
| User entered empty. | Taylor Atkinson (b) (4) | 19 Apr 2021 19:29:17 |

**US3902021**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 10:17:24**

[AE start date and time \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 30 Apr 2021 16:09:19 |
| User entered empty. | System           | 19 Apr 2021 19:29:17 |

**US3902021**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 10:17:24**

[Ongoing?](#)

| Audit                 | User                    | Time (GMT)           |
|-----------------------|-------------------------|----------------------|
| Data hard locked.     | (b) (4), (b) (6)        | 30 Apr 2021 16:09:19 |
| User entered 'No (N)' | Taylor Atkinson (b) (4) | 19 Apr 2021 19:29:17 |



**US3902021**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 10:17:24**

*If not Ongoing, end date (dd MMM yyyy)*

| Audit                      | User                    | Time (GMT)           |
|----------------------------|-------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)        | 30 Apr 2021 16:09:19 |
| User entered '10 Oct 2020' | Taylor Atkinson (b) (4) | 19 Apr 2021 19:29:17 |
|                            | (b) (4)                 |                      |

**US3902021**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 10:17:24**

[End time \(00:00-23:59\)](#)

| Audit               | User                    | Time (GMT)           |
|---------------------|-------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)        | 30 Apr 2021 16:09:19 |
| User entered empty. | Taylor Atkinson (b) (4) | 19 Apr 2021 19:29:17 |

**US3902021**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 10:17:24**

[AE End Date and Time \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 30 Apr 2021 16:09:19 |
| User entered empty. | System           | 19 Apr 2021 19:29:17 |

**US3902021**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 10:17:24**

[Severity](#)

| Audit                                      | User                               | Time (GMT)           |
|--|------------------------------------|----------------------|
| Data hard locked.                          | (b) (4), (b) (6)                   | 30 Apr 2021 16:09:19 |
| User entered 'Grade 1/Mild (Grade 1/Mild)' | Taylor Atkinson (b) (4)<br>(b) (4) | 19 Apr 2021 19:29:17 |

**US3902021**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 10:17:24**

[Is the adverse event serious?](#)

| Audit                 | User                    | Time (GMT)           |
|-----------------------|-------------------------|----------------------|
| Data hard locked.     | (b) (4), (b) (6)        | 30 Apr 2021 16:09:19 |
| User entered 'No (N)' | Taylor Atkinson (b) (4) | 19 Apr 2021 19:29:17 |

**US3902021**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 10:17:24**

[Death](#)

| Audit             | User                    | Time (GMT)           |
|-------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6)        | 30 Apr 2021 16:09:19 |
| User entered '0'  | Taylor Atkinson (b) (4) | 19 Apr 2021 19:29:17 |

**US3902021**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 10:17:24**

[Life threatening](#)

| Audit             | User                    | Time (GMT)           |
|-------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6)        | 30 Apr 2021 16:09:19 |
| User entered '0'  | Taylor Atkinson (b) (4) | 19 Apr 2021 19:29:17 |

**US3902021**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 10:17:24**

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit             | User                    | Time (GMT)           |
|-------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6)        | 30 Apr 2021 16:09:19 |
| User entered '0'  | Taylor Atkinson (b) (4) | 19 Apr 2021 19:29:17 |
|                   | (b) (4)                 |                      |



**US3902021**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 10:17:24**

**Hospital Admission Date** (*dd MMM yyyy*)

| Audit               | User                    | Time (GMT)           |
|---------------------|-------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)        | 30 Apr 2021 16:09:19 |
| User entered empty. | Taylor Atkinson (b) (4) | 19 Apr 2021 19:29:17 |

**US3902021**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 10:17:24**

[Hospital Discharge Date \(dd MMM yyyy\)](#)

| Audit               | User                    | Time (GMT)           |
|---------------------|-------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)        | 30 Apr 2021 16:09:19 |
| User entered empty. | Taylor Atkinson (b) (4) | 19 Apr 2021 19:29:17 |

**US3902021**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 10:17:24**

[Admitted to ICU?](#)

| Audit               | User                    | Time (GMT)           |
|---------------------|-------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)        | 30 Apr 2021 16:09:19 |
| User entered empty. | Taylor Atkinson (b) (4) | 19 Apr 2021 19:29:17 |

**US3902021**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 10:17:24**

[Number of Days in ICU](#)

| Audit               | User                               | Time (GMT)           |
|---------------------|------------------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)                   | 30 Apr 2021 16:09:19 |
| User entered empty. | Taylor Atkinson (b) (4)<br>(b) (4) | 19 Apr 2021 19:29:17 |

**US3902021**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 10:17:24**

[Persistent or significant disability or incapacity](#)

| Audit             | User                    | Time (GMT)           |
|-------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6)        | 30 Apr 2021 16:09:19 |
| User entered '0'  | Taylor Atkinson (b) (4) | 19 Apr 2021 19:29:17 |

**US3902021**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 10:17:24**

[Congenital anomaly or birth defect](#)

| Audit             | User                    | Time (GMT)           |
|-------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6)        | 30 Apr 2021 16:09:19 |
| User entered '0'  | Taylor Atkinson (b) (4) | 19 Apr 2021 19:29:17 |

**US3902021**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 10:17:24**

[Other medically important event](#)

| Audit             | User                    | Time (GMT)           |
|-------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6)        | 30 Apr 2021 16:09:19 |
| User entered '0'  | Taylor Atkinson (b) (4) | 19 Apr 2021 19:29:17 |

**US3902021**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 10:17:24**

[Relationship to investigational product](#)

| Audit                            | User                               | Time (GMT)           |
|----------------------------------|------------------------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6)                   | 30 Apr 2021 16:09:19 |
| User entered 'Related (RELATED)' | Taylor Atkinson (b) (4)<br>(b) (4) | 19 Apr 2021 19:29:17 |



**US3902021**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 10:17:24**

[Relationship to Study Procedure](#)

| Audit                                    | User                               | Time (GMT)           |
|--|------------------------------------|----------------------|
| Data hard locked.                        | (b) (4), (b) (6)                   | 30 Apr 2021 16:09:19 |
| User entered 'Not Related (NOT RELATED)' | Taylor Atkinson (b) (4)<br>(b) (4) | 19 Apr 2021 19:29:17 |

**US3902021**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 10:17:24**

[Action taken with investigational product](#)

| Audit                      | User                    | Time (GMT)           |
|----------------------------|-------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)        | 30 Apr 2021 16:09:19 |
| User entered 'None (NONE)' | Taylor Atkinson (b) (4) | 19 Apr 2021 19:29:17 |

**US3902021**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 10:17:24**

[None](#)

| Audit             | User                    | Time (GMT)           |
|-------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6)        | 30 Apr 2021 16:09:19 |
| User entered '1'  | Taylor Atkinson (b) (4) | 19 Apr 2021 19:29:17 |

**US3902021**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 10:17:24**

[Concomitant Medication](#)

| Audit             | User                    | Time (GMT)           |
|-------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6)        | 30 Apr 2021 16:09:19 |
| User entered '0'  | Taylor Atkinson (b) (4) | 19 Apr 2021 19:29:17 |

**US3902021**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 10:17:24**

[Concomitant Procedure](#)

| Audit             | User                    | Time (GMT)           |
|-------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6)        | 30 Apr 2021 16:09:19 |
| User entered '0'  | Taylor Atkinson (b) (4) | 19 Apr 2021 19:29:17 |

**US3902021**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 10:17:24**

[Outcome](#)

| Audit  | User                               | Time (GMT)           |
|--|------------------------------------|----------------------|
| Data hard locked.                                      | (b) (4), (b) (6)                   | 30 Apr 2021 16:09:19 |
| User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' | Taylor Atkinson (b) (4)<br>(b) (4) | 19 Apr 2021 19:29:17 |

**US3902021**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 10:17:24**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

| Audit               | User                               | Time (GMT)           |
|---------------------|------------------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)                   | 30 Apr 2021 16:09:19 |
| User entered empty. | Taylor Atkinson (b) (4)<br>(b) (4) | 19 Apr 2021 19:29:17 |

**US3902021**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 10:17:24**

[Narrative](#)

| Audit               | User                    | Time (GMT)           |
|---------------------|-------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)        | 30 Apr 2021 16:09:19 |
| User entered empty. | Taylor Atkinson (b) (4) | 19 Apr 2021 19:29:17 |



**US3902021**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 10:17:24**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 16:09:19 |
| User entered '0'  | System           | 19 Apr 2021 19:29:17 |

**US3902021**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 10:17:24**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 16:09:19 |
| User entered '0'  | System           | 19 Apr 2021 19:29:17 |

**US3902021**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 10:17:24**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 16:09:19 |

US3902021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 10:17:24

Were any prior/concomitant medications and/or vaccinations taken?

| Audit  | User                    | Time (GMT)           |
|--|-------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)        | 04 May 2021 04:33:38 |
| User signature succeeded.  | Murray Kimmel (b) (4)   | 30 Mar 2021 18:10:57 |
| User closed query 'Per DM CLR: Per Diary Dose 2 Day 2, Pain at Injection Site = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' (Site from DM).<br>Query 'Per DM CLR: Per Diary Dose 2 Day 2, Pain at Injection Site = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' answered with 'subject took ibuprofen which is already in conmeds.' (Site from DM). | (b) (4), (b) (6)        | 22 Feb 2021 05:26:02 |
| User opened query 'Per DM CLR: Per Diary Dose 2 Day 2, Pain at Injection Site = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' (Site from DM).<br>User entered 'Yes (Y)'   | Bram Swarr (b) (4)      | 19 Feb 2021 21:17:40 |
|  | (b) (4), (b) (6)        | 10 Feb 2021 06:09:30 |
|  | Taylor Atkinson (b) (4) | 07 Oct 2020 17:00:56 |
|  | (b) (4)                 |                      |

US3902021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:17:24

[Name of Medication](#)

| Audit  | User   | Time (GMT)                                   |
|--|--|--|
| Data hard locked.  | (b) (4), (b) (6)                             | 01 May 2021 16:50:21                         |
| User signature succeeded.  | Murray Kimmel (b) (4)                        | 30 Mar 2021 18:10:57                         |
| 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>version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4)              | 07 Oct 2020 17:04:16                         |
| 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)              | 07 Oct 2020 17:04:16                         |
| Data point term sent to Coder<br>User entered 'Ibuprofen'  | System<br>Taylor Atkinson (b) (4)<br>(b) (4) | 07 Oct 2020 17:03:13<br>07 Oct 2020 17:03:09 |

**US3902021**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 10:17:24**

[Prophylaxis](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 01 May 2021 16:50:21 |
| User signature succeeded. | Murray Kimmel (b) (4)   | 30 Mar 2021 18:10:57 |
| User entered 'No (N)'     | Taylor Atkinson (b) (4) | 07 Oct 2020 17:03:09 |

US3902021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:17:24

[Indication](#)

| Audit  | User                  | Time (GMT)           |
|--|-----------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)      | 01 May 2021 16:50:21 |
| User signature succeeded.  | Murray Kimmel (b) (4) | 30 Mar 2021 18:10:57 |
| 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).   | (b) (4), (b) (6)      | 14 Dec 2020 08:16:27 |
| 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 'site confirms headache did not meat AE criteria' (Site from DM). | Bram Swarr (b) (4)    | 12 Dec 2020 16:18:10 |





US3902021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:17:24

[Dose per administration](#)

| Audit  | User                    | Time (GMT)           |
|--|-------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)        | 01 May 2021 16:50:21 |
| User signature succeeded.  | Murray Kimmel (b) (4)   | 30 Mar 2021 18:10:57 |
| User closed query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).             | (b) (4), (b) (6)        | 19 Mar 2021 11:32:05 |
| Query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' answered with 'updated' (Site from DM). | Taylor Atkinson (b) (4) | 17 Mar 2021 12:27:30 |
| User entered '400' reason for change: Data Entry Error   | (b) (4)                 | 17 Mar 2021 12:27:25 |
| User opened query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).             | (b) (4), (b) (6)        | 06 Mar 2021 08:03:55 |
| User entered '500'   | Taylor Atkinson (b) (4) | 07 Oct 2020 17:03:09 |

**US3902021**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 10:17:24**

[Dose unit](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 01 May 2021 16:50:21 |
| User signature succeeded. | Murray Kimmel (b) (4)   | 30 Mar 2021 18:10:57 |
| User entered 'mg (mg)'    | Taylor Atkinson (b) (4) | 07 Oct 2020 17:03:09 |

**US3902021**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 10:17:24**

[If dose unit is Other, specify](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 01 May 2021 16:50:21 |
| User signature succeeded. | Murray Kimmel (b) (4)   | 30 Mar 2021 18:10:57 |
| User entered empty.       | Taylor Atkinson (b) (4) | 07 Oct 2020 17:03:09 |

**US3902021**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 10:17:24**

[Frequency](#)

| Audit                          | User                    | Time (GMT)           |
|--------------------------------|-------------------------|----------------------|
| Data hard locked.              | (b) (4), (b) (6)        | 01 May 2021 16:50:21 |
| User signature succeeded.      | Murray Kimmel (b) (4)   | 30 Mar 2021 18:10:57 |
| User entered 'as needed (PRN)' | Taylor Atkinson (b) (4) | 07 Oct 2020 17:03:09 |

**US3902021**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 10:17:24**

[If frequency is Other, specify](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 01 May 2021 16:50:21 |
| User signature succeeded. | Murray Kimmel (b) (4)   | 30 Mar 2021 18:10:57 |
| User entered empty.       | Taylor Atkinson (b) (4) | 07 Oct 2020 17:03:09 |

**US3902021**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 10:17:24**

[Route of administration](#)

| Audit                      | User                    | Time (GMT)           |
|----------------------------|-------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)        | 01 May 2021 16:50:21 |
| User signature succeeded.  | Murray Kimmel (b) (4)   | 30 Mar 2021 18:10:57 |
| User entered 'Oral (ORAL)' | Taylor Atkinson (b) (4) | 07 Oct 2020 17:03:09 |

**US3902021**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 10:17:24**

[If route of administration is Other, specify](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 01 May 2021 16:50:21 |
| User signature succeeded. | Murray Kimmel (b) (4)   | 30 Mar 2021 18:10:57 |
| User entered empty.       | Taylor Atkinson (b) (4) | 07 Oct 2020 17:03:09 |

**US3902021**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 10:17:24**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                    | Time (GMT)           |
|----------------------------|-------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)        | 01 May 2021 16:50:21 |
| User signature succeeded.  | Murray Kimmel (b) (4)   | 30 Mar 2021 18:10:57 |
| User entered '30 Sep 2020' | Taylor Atkinson (b) (4) | 07 Oct 2020 17:03:09 |



**US3902021**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 10:17:24**

[Start date completely unknown](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 01 May 2021 16:50:21 |
| User signature succeeded. | Murray Kimmel (b) (4)   | 30 Mar 2021 18:10:57 |
| User entered '0'          | Taylor Atkinson (b) (4) | 07 Oct 2020 17:03:09 |

**US3902021**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 10:17:24**

[Ongoing?](#)

| Audit   | User                    | Time (GMT)           |
|---|-------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)        | 01 May 2021 16:50:21 |
| User signature succeeded.                                 | Murray Kimmel (b) (4)   | 30 Mar 2021 18:10:57 |
| User entered 'No (N)' reason for change: Data Entry Error | Bram Swarr (b) (4)      | 19 Feb 2021 21:17:26 |
| User entered 'Yes (Y)'                                    | Taylor Atkinson (b) (4) | 07 Oct 2020 17:03:09 |

**US3902021**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 10:17:24**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit  | User                    | Time (GMT)           |
|--|-------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)        | 01 May 2021 16:50:21 |
| User signature succeeded.                                      | Murray Kimmel (b) (4)   | 30 Mar 2021 18:10:57 |
| User entered '10 Oct 2020' reason for change: Data Entry Error | Bram Swarr (b) (4)      | 19 Feb 2021 21:17:26 |
| User entered empty.  | Taylor Atkinson (b) (4) | 07 Oct 2020 17:03:09 |

**US3902021**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 10:17:24**

[Was this medication taken for solicited event?](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 01 May 2021 16:50:21 |
| User signature succeeded. | Murray Kimmel (b) (4)   | 30 Mar 2021 18:10:57 |
| User entered 'Yes (Y)'    | Taylor Atkinson (b) (4) | 07 Oct 2020 17:03:09 |

**US3902021**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 10:17:24**

[Separate Dosage Number \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 01 May 2021 16:50:21 |
| User entered empty. | System           | 07 Oct 2020 17:03:09 |

**US3902021**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 10:17:24**

[Interval Dosage Unit Number \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 01 May 2021 16:50:21 |
| User entered empty. | System           | 07 Oct 2020 17:03:09 |

**US3902021**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 10:17:24**

[Interval Dosage Definition \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 01 May 2021 16:50:21 |
| User entered empty. | System           | 07 Oct 2020 17:03:09 |

US3902021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:17:24

[Name of Medication](#)

| Audit  | User                    | Time (GMT)           |
|--|-------------------------|----------------------|
| User signature succeeded.  | Murray Kimmel (b) (4)   | 30 Mar 2021 18:10:57 |
|  |                         |                      |
| User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: OXYCODONE;PARACETAMOL - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)    | 18 Mar 2021 13:00:37 |
|  |                         |                      |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.   | Coder Import (b) (4)    | 18 Mar 2021 13:00:37 |
|  |                         |                      |
| Data point term sent to Coder  | System                  | 02 Mar 2021 00:57:12 |
| User entered 'oxycodone/acetaminophen'   | Katrina Carlson (b) (4) | 02 Mar 2021 00:56:58 |
|  |                         |                      |



**US3902021**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 10:17:24**

[Prophylaxis](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Murray Kimmel (b) (4)   | 30 Mar 2021 18:10:57 |
|                           |                         |                      |
| User entered 'No (N)'     | Katrina Carlson (b) (4) | 02 Mar 2021 00:56:58 |
|                           | (b) (4)                 |                      |

**US3902021**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 10:17:24**

[Indication](#)

| Audit                         | User                    | Time (GMT)           |
|-------------------------------|-------------------------|----------------------|
| User signature succeeded.     | Murray Kimmel (b) (4)   | 30 Mar 2021 18:10:57 |
|                               |                         |                      |
| User entered 'cholelithiasis' | Katrina Carlson (b) (4) | 02 Mar 2021 00:56:58 |
|                               | (b) (4)                 |                      |

**US3902021**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 10:17:24**

[Dose per administration](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Murray Kimmel (b) (4)   | 30 Mar 2021 18:10:57 |
|                           |                         |                      |
| User entered '5/325'      | Katrina Carlson (b) (4) | 02 Mar 2021 00:56:58 |
|                           | (b) (4)                 |                      |

**US3902021**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 10:17:24**

[Dose unit](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Murray Kimmel (b) (4)   | 30 Mar 2021 18:10:57 |
|                           |                         |                      |
| User entered 'mg (mg)'    | Katrina Carlson (b) (4) | 02 Mar 2021 00:56:58 |
|                           | (b) (4)                 |                      |

**US3902021**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 10:17:24**

[If dose unit is Other, specify](#)

| Audit                     | User                                  | Time (GMT)           |
|---------------------------|---------------------------------------|----------------------|
| User signature succeeded. | Murray Kimmel (b) (4)<br>[REDACTED]   | 30 Mar 2021 18:10:57 |
| User entered empty.       | Katrina Carlson (b) (4)<br>[REDACTED] | 02 Mar 2021 00:56:58 |

**US3902021**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 10:17:24**

[Frequency](#)

| Audit                          | User                    | Time (GMT)           |
|--------------------------------|-------------------------|----------------------|
| User signature succeeded.      | Murray Kimmel (b) (4)   | 30 Mar 2021 18:10:57 |
|                                |                         |                      |
| User entered 'as needed (PRN)' | Katrina Carlson (b) (4) | 02 Mar 2021 00:56:58 |
|                                | (b) (4)                 |                      |

**US3902021**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 10:17:24**

[If frequency is Other, specify](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| User signature succeeded. | Murray Kimmel (b) (4)<br>[REDACTED] | 30 Mar 2021 18:10:57 |
| User entered empty.       | Katrina Carlson (b) (4)<br>(b) (4)  | 02 Mar 2021 00:56:58 |

**US3902021**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 10:17:24**

[Route of administration](#)

| Audit                      | User                    | Time (GMT)           |
|----------------------------|-------------------------|----------------------|
| User signature succeeded.  | Murray Kimmel (b) (4)   | 30 Mar 2021 18:10:57 |
|                            |                         |                      |
| User entered 'Oral (ORAL)' | Katrina Carlson (b) (4) | 02 Mar 2021 00:56:58 |
|                            | (b) (4)                 |                      |



**US3902021**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 10:17:24**

[If route of administration is Other, specify](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| User signature succeeded. | Murray Kimmel (b) (4)<br>[REDACTED] | 30 Mar 2021 18:10:57 |
| User entered empty.       | Katrina Carlson (b) (4)<br>(b) (4)  | 02 Mar 2021 00:56:58 |

**US3902021**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 10:17:24**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                    | Time (GMT)           |
|----------------------------|-------------------------|----------------------|
| User signature succeeded.  | Murray Kimmel (b) (4)   | 30 Mar 2021 18:10:57 |
|                            |                         |                      |
| User entered '25 Feb 2021' | Katrina Carlson (b) (4) | 02 Mar 2021 00:56:58 |
|                            | (b) (4)                 |                      |

**US3902021**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 10:17:24**

[Start date completely unknown](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Murray Kimmel (b) (4)   | 30 Mar 2021 18:10:57 |
|                           |                         |                      |
| User entered '0'          | Katrina Carlson (b) (4) | 02 Mar 2021 00:56:58 |
|                           | (b) (4)                 |                      |

**US3902021**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 10:17:24**

[Ongoing?](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Murray Kimmel (b) (4)   | 30 Mar 2021 18:10:57 |
|                           |                         |                      |
| User entered 'Yes (Y)'    | Katrina Carlson (b) (4) | 02 Mar 2021 00:56:58 |
|                           | (b) (4)                 |                      |

**US3902021**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 10:17:24**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| User signature succeeded. | Murray Kimmel (b) (4)<br>[REDACTED] | 30 Mar 2021 18:10:57 |
| User entered empty.       | Katrina Carlson (b) (4)<br>(b) (4)  | 02 Mar 2021 00:56:58 |

**US3902021**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 10:17:24**

[Was this medication taken for solicited event?](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| User signature succeeded. | Murray Kimmel (b) (4)<br>[REDACTED] | 30 Mar 2021 18:10:57 |
| User entered 'No (N)'     | Katrina Carlson (b) (4)<br>(b) (4)  | 02 Mar 2021 00:56:58 |

**US3902021**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 10:17:24**

[Separate Dosage Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 02 Mar 2021 00:56:58 |

**US3902021**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 10:17:24**

[Interval Dosage Unit Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 02 Mar 2021 00:56:58 |



**US3902021**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 10:17:24**

[Interval Dosage Definition \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 02 Mar 2021 00:56:58 |

US3902021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:17:24

[Name of Medication](#)

| Audit  | User                    | Time (GMT)           |
|--|-------------------------|----------------------|
| User signature succeeded.  | Murray Kimmel (b) (4)   | 30 Mar 2021 18:10:57 |
|  | (b) (4)                 |                      |
| User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: BETA-LACTAM ANTIBACTERIALS, PENICILLINS, ATC: COMBINATIONS OF PENICILLINS, INCL. BETA-LACTAMASE INHIBITORS, PRODUCT: AMOXICILLIN;CLAVULANATE POTASSIUM, PRODUCTSYNONYM: AUGMENTIN [AMOXICILLIN;CLAVULANATE POTASSIUM] - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)    | 04 Mar 2021 07:38:04 |
|  | (b) (4)                 |                      |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.   | Coder Import (b) (4)    | 04 Mar 2021 07:38:04 |
|  | (b) (4)                 |                      |
| Data point term sent to Coder  | System                  | 02 Mar 2021 01:04:18 |
| User entered 'AMOXICILLIN/potassium CLAVULANATE (augmentin)'   | Katrina Carlson (b) (4) | 02 Mar 2021 01:03:18 |
|  | (b) (4)                 |                      |

**US3902021**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 10:17:24**

[Prophylaxis](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Murray Kimmel (b) (4)   | 30 Mar 2021 18:10:57 |
|                           |                         |                      |
| User entered 'No (N)'     | Katrina Carlson (b) (4) | 02 Mar 2021 01:03:18 |
|                           | (b) (4)                 |                      |

**US3902021**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 10:17:24**

[Indication](#)

| Audit                         | User                    | Time (GMT)           |
|-------------------------------|-------------------------|----------------------|
| User signature succeeded.     | Murray Kimmel (b) (4)   | 30 Mar 2021 18:10:57 |
|                               |                         |                      |
| User entered 'cholelithiasis' | Katrina Carlson (b) (4) | 02 Mar 2021 01:03:18 |
|                               | (b) (4)                 |                      |

**US3902021**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 10:17:24**

[Dose per administration](#)

| Audit                     | User                                  | Time (GMT)           |
|---------------------------|---------------------------------------|----------------------|
| User signature succeeded. | Murray Kimmel (b) (4)<br>[REDACTED]   | 30 Mar 2021 18:10:57 |
| User entered '875/125'    | Katrina Carlson (b) (4)<br>[REDACTED] | 02 Mar 2021 01:03:18 |

**US3902021**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 10:17:24**

[Dose unit](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Murray Kimmel (b) (4)   | 30 Mar 2021 18:10:57 |
|                           |                         |                      |
| User entered 'mg (mg)'    | Katrina Carlson (b) (4) | 02 Mar 2021 01:03:18 |
|                           | (b) (4)                 |                      |

**US3902021**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 10:17:24**

[If dose unit is Other, specify](#)

| Audit                     | User                                  | Time (GMT)           |
|---------------------------|---------------------------------------|----------------------|
| User signature succeeded. | Murray Kimmel (b) (4)<br>[REDACTED]   | 30 Mar 2021 18:10:57 |
| User entered empty.       | Katrina Carlson (b) (4)<br>[REDACTED] | 02 Mar 2021 01:03:18 |

**US3902021**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 10:17:24**

[Frequency](#)

| Audit                            | User                    | Time (GMT)           |
|----------------------------------|-------------------------|----------------------|
| User signature succeeded.        | Murray Kimmel (b) (4)   | 30 Mar 2021 18:10:57 |
|                                  |                         |                      |
| User entered 'twice daily (BID)' | Katrina Carlson (b) (4) | 02 Mar 2021 01:03:18 |
|                                  | (b) (4)                 |                      |



**US3902021**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 10:17:24**

[If frequency is Other, specify](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| User signature succeeded. | Murray Kimmel (b) (4)<br>[REDACTED] | 30 Mar 2021 18:10:57 |
| User entered empty.       | Katrina Carlson (b) (4)<br>(b) (4)  | 02 Mar 2021 01:03:18 |

**US3902021**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 10:17:24**

[Route of administration](#)

| Audit                      | User                    | Time (GMT)           |
|----------------------------|-------------------------|----------------------|
| User signature succeeded.  | Murray Kimmel (b) (4)   | 30 Mar 2021 18:10:57 |
|                            |                         |                      |
| User entered 'Oral (ORAL)' | Katrina Carlson (b) (4) | 02 Mar 2021 01:03:18 |
|                            | (b) (4)                 |                      |

**US3902021**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 10:17:24**

If route of administration is Other, specify

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Murray Kimmel (b) (4)   | 30 Mar 2021 18:10:57 |
|                           |                         |                      |
| User entered empty.       | Katrina Carlson (b) (4) | 02 Mar 2021 01:03:18 |
|                           | (b) (4)                 |                      |

**US3902021**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 10:17:24**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                    | Time (GMT)           |
|----------------------------|-------------------------|----------------------|
| User signature succeeded.  | Murray Kimmel (b) (4)   | 30 Mar 2021 18:10:57 |
|                            |                         |                      |
| User entered '25 Feb 2021' | Katrina Carlson (b) (4) | 02 Mar 2021 01:03:18 |
|                            | (b) (4)                 |                      |

**US3902021**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 10:17:24**

[Start date completely unknown](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Murray Kimmel (b) (4)   | 30 Mar 2021 18:10:57 |
|                           |                         |                      |
| User entered '0'          | Katrina Carlson (b) (4) | 02 Mar 2021 01:03:18 |
|                           | (b) (4)                 |                      |

**US3902021**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 10:17:24**

[Ongoing?](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Murray Kimmel (b) (4)   | 30 Mar 2021 18:10:57 |
|                           |                         |                      |
| User entered 'Yes (Y)'    | Katrina Carlson (b) (4) | 02 Mar 2021 01:03:18 |
|                           | (b) (4)                 |                      |

**US3902021**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 10:17:24**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Murray Kimmel (b) (4)   | 30 Mar 2021 18:10:57 |
|                           |                         |                      |
| User entered empty.       | Katrina Carlson (b) (4) | 02 Mar 2021 01:03:18 |
|                           | (b) (4)                 |                      |

**US3902021**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 10:17:24**

[Was this medication taken for solicited event?](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| User signature succeeded. | Murray Kimmel (b) (4)<br>[REDACTED] | 30 Mar 2021 18:10:57 |
| User entered 'No (N)'     | Katrina Carlson (b) (4)<br>(b) (4)  | 02 Mar 2021 01:03:18 |



**US3902021**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 10:17:24**

[Separate Dosage Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '2' | System | 02 Mar 2021 01:03:18 |

**US3902021**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 10:17:24**

[Interval Dosage Unit Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 02 Mar 2021 01:03:18 |

**US3902021**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 10:17:24**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User   | Time (GMT)           |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 02 Mar 2021 01:03:18 |

US3902021

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 10:17:24

[Were any concomitant procedures performed?](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 04 May 2021 04:53:23 |
| User signature succeeded. | Murray Kimmel (b) (4)   | 30 Mar 2021 18:10:57 |
| User entered 'Yes (Y)'    | Katrina Carlson (b) (4) | 02 Mar 2021 01:03:28 |

US3902021

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 10:17:24

Procedure/Surgery date (*dd MMM yyyy*)

| Audit                      | User                                  | Time (GMT)           |
|----------------------------|---------------------------------------|----------------------|
| User signature succeeded.  | Murray Kimmel (b) (4)<br>[REDACTED]   | 30 Mar 2021 18:10:57 |
| User entered '23 Feb 2021' | Katrina Carlson (b) (4)<br>[REDACTED] | 02 Mar 2021 01:04:06 |

US3902021

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 10:17:24

[Procedure/Surgery](#)

| Audit                          | User                    | Time (GMT)           |
|--------------------------------|-------------------------|----------------------|
| User signature succeeded.      | Murray Kimmel (b) (4)   | 30 Mar 2021 18:10:57 |
|                                |                         |                      |
| User entered 'Cholecystectomy' | Katrina Carlson (b) (4) | 02 Mar 2021 01:04:06 |
|                                | (b) (4)                 |                      |

**US3902021**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (1)**

**Generated On: 10 Jun 2021 10:17:24**

[Indication](#)

| Audit                             | User                    | Time (GMT)           |
|-----------------------------------|-------------------------|----------------------|
| User signature succeeded.         | Murray Kimmel (b) (4)   | 30 Mar 2021 18:10:57 |
|                                   |                         |                      |
| User entered 'Adverse Event (AE)' | Katrina Carlson (b) (4) | 02 Mar 2021 01:04:06 |
|                                   | (b) (4)                 |                      |

US3902021

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (1)**

**Generated On: 10 Jun 2021 10:17:24**

[If indication is Other, specify](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| User signature succeeded. | Murray Kimmel (b) (4)<br>[REDACTED] | 30 Mar 2021 18:10:57 |
| User entered empty.       | Katrina Carlson (b) (4)<br>(b) (4)  | 02 Mar 2021 01:04:06 |



**US3902021**

**Folder: SAE USA-US210-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:17:24**

[SAEID](#)

| Audit   | User                  | Time (GMT)           |
|---|-----------------------|----------------------|
| User signature succeeded.                             | Murray Kimmel (b) (4) | 30 Mar 2021 18:10:57 |
|   |                       |                      |
| Reviewed for Safety.                                  | (b) (4), (b) (6)      | 02 Mar 2021 15:39:31 |
|   |                       |                      |
| User entered<br>'USA-US210-2021-MRNA-1273-P301000002' | System                | 02 Mar 2021 15:38:31 |

**US3902021**

**Folder: SAE USA-US210-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:17:24**

**Serious**

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Murray Kimmel (b) (4) | 30 Mar 2021 18:10:57 |
|                           |                       |                      |
| Reviewed for Safety.      | (b) (4), (b) (6)      | 02 Mar 2021 15:39:35 |
|                           |                       |                      |
| User entered 'Yes (Y)'    | System                | 02 Mar 2021 15:38:31 |

**US3902021**

**Folder: SAE USA-US210-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:17:24**

[Death](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Murray Kimmel (b) (4) | 30 Mar 2021 18:10:57 |
|                           |                       |                      |
| Reviewed for Safety.      | (b) (4), (b) (6)      | 02 Mar 2021 15:39:35 |
|                           |                       |                      |
| User entered 'No (N)'     | System                | 02 Mar 2021 15:38:31 |

**US3902021**

**Folder: SAE USA-US210-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:17:24**

[Life threatening](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Murray Kimmel (b) (4) | 30 Mar 2021 18:10:57 |
|                           |                       |                      |
| Reviewed for Safety.      | (b) (4), (b) (6)      | 02 Mar 2021 15:39:35 |
|                           |                       |                      |
| User entered 'No (N)'     | System                | 02 Mar 2021 15:38:31 |

**US3902021**

**Folder: SAE USA-US210-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:17:24**

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Murray Kimmel (b) (4) | 30 Mar 2021 18:10:57 |
|                           |                       |                      |
| Reviewed for Safety.      | (b) (4), (b) (6)      | 02 Mar 2021 15:39:35 |
|                           |                       |                      |
| User entered 'Yes (Y)'    | System                | 02 Mar 2021 15:38:31 |

**US3902021**

**Folder: SAE USA-US210-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:17:24**

[Persistent or significant disability or incapacity](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Murray Kimmel (b) (4) | 30 Mar 2021 18:10:57 |
|                           |                       |                      |
| Reviewed for Safety.      | (b) (4), (b) (6)      | 02 Mar 2021 15:39:35 |
|                           |                       |                      |
| User entered 'No (N)'     | System                | 02 Mar 2021 15:38:31 |

**US3902021**

**Folder: SAE USA-US210-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:17:24**

[Congenital anomaly or birth defect](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Murray Kimmel (b) (4) | 30 Mar 2021 18:10:57 |
|                           |                       |                      |
| Reviewed for Safety.      | (b) (4), (b) (6)      | 02 Mar 2021 15:39:35 |
|                           |                       |                      |
| User entered 'No (N)'     | System                | 02 Mar 2021 15:38:31 |

**US3902021**

**Folder: SAE USA-US210-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:17:24**

[Other medically important event](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Murray Kimmel (b) (4) | 30 Mar 2021 18:10:57 |
|                           |                       |                      |
| Reviewed for Safety.      | (b) (4), (b) (6)      | 02 Mar 2021 15:39:35 |
|                           |                       |                      |
| User entered 'No (N)'     | System                | 02 Mar 2021 15:38:31 |



**US3902021**

**Folder: SAE USA-US210-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:17:24**

[Investigator's First Name](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Murray Kimmel (b) (4) | 30 Mar 2021 18:10:57 |
|                           |                       |                      |
| Reviewed for Safety.      | (b) (4), (b) (6)      | 02 Mar 2021 15:39:35 |
|                           |                       |                      |
| User entered 'Murray'     | System                | 02 Mar 2021 15:38:31 |

**US3902021**

**Folder: SAE USA-US210-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:17:24**

[Investigator's Last Name](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Murray Kimmel (b) (4) | 30 Mar 2021 18:10:57 |
|                           |                       |                      |
| Reviewed for Safety.      | (b) (4), (b) (6)      | 02 Mar 2021 15:39:35 |
|                           |                       |                      |
| User entered 'Kimmel'     | System                | 02 Mar 2021 15:38:31 |

**US3902021**

**Folder: SAE USA-US210-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:17:24**

[Investigator Country](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Murray Kimmel (b) (4) | 30 Mar 2021 18:10:57 |
|                           |                       |                      |
| Reviewed for Safety.      | (b) (4), (b) (6)      | 02 Mar 2021 15:39:35 |
|                           |                       |                      |
| User entered 'US'         | System                | 02 Mar 2021 15:39:24 |

**US3902021**

**Folder: SAE USA-US210-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:17:24**

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '2' | System | 18 Mar 2021 16:40:23 |
| User entered '1' | System | 02 Mar 2021 15:39:24 |

**US3902021**

**Folder: SAE USA-US210-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:17:24**

[SAEID](#)

| Audit   | User                  | Time (GMT)           |
|---|-----------------------|----------------------|
| User signature succeeded.                             | Murray Kimmel (b) (4) | 30 Mar 2021 18:10:57 |
|   |                       |                      |
| Reviewed for Safety.                                  | (b) (4), (b) (6)      | 02 Mar 2021 15:39:31 |
|   |                       |                      |
| User entered<br>'USA-US210-2021-MRNA-1273-P301000002' | System                | 02 Mar 2021 15:38:31 |

**US3902021**

**Folder: SAE USA-US210-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:17:24**

**Serious**

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Murray Kimmel (b) (4) | 30 Mar 2021 18:10:57 |
|                           |                       |                      |
| Reviewed for Safety.      | (b) (4), (b) (6)      | 02 Mar 2021 15:39:35 |
|                           |                       |                      |
| User entered 'Yes (Y)'    | System                | 02 Mar 2021 15:38:31 |

**US3902021**

**Folder: SAE USA-US210-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:17:24**

[Death](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Murray Kimmel (b) (4) | 30 Mar 2021 18:10:57 |
|                           |                       |                      |
| Reviewed for Safety.      | (b) (4), (b) (6)      | 02 Mar 2021 15:39:35 |
|                           |                       |                      |
| User entered 'No (N)'     | System                | 02 Mar 2021 15:38:31 |

**US3902021**

**Folder: SAE USA-US210-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:17:24**

[Life threatening](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Murray Kimmel (b) (4) | 30 Mar 2021 18:10:57 |
|                           |                       |                      |
| Reviewed for Safety.      | (b) (4), (b) (6)      | 02 Mar 2021 15:39:35 |
|                           |                       |                      |
| User entered 'No (N)'     | System                | 02 Mar 2021 15:38:31 |



**US3902021**

**Folder: SAE USA-US210-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:17:24**

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Murray Kimmel (b) (4) | 30 Mar 2021 18:10:57 |
|                           |                       |                      |
| Reviewed for Safety.      | (b) (4), (b) (6)      | 02 Mar 2021 15:39:35 |
|                           |                       |                      |
| User entered 'Yes (Y)'    | System                | 02 Mar 2021 15:38:31 |

**US3902021**

**Folder: SAE USA-US210-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:17:24**

[Persistent or significant disability or incapacity](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Murray Kimmel (b) (4) | 30 Mar 2021 18:10:57 |
|                           |                       |                      |
| Reviewed for Safety.      | (b) (4), (b) (6)      | 02 Mar 2021 15:39:35 |
|                           |                       |                      |
| User entered 'No (N)'     | System                | 02 Mar 2021 15:38:31 |

**US3902021**

**Folder: SAE USA-US210-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:17:24**

[Congenital anomaly or birth defect](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Murray Kimmel (b) (4) | 30 Mar 2021 18:10:57 |
|                           |                       |                      |
| Reviewed for Safety.      | (b) (4), (b) (6)      | 02 Mar 2021 15:39:35 |
|                           |                       |                      |
| User entered 'No (N)'     | System                | 02 Mar 2021 15:38:31 |

**US3902021**

**Folder: SAE USA-US210-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:17:24**

[Other medically important event](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Murray Kimmel (b) (4) | 30 Mar 2021 18:10:57 |
|                           |                       |                      |
| Reviewed for Safety.      | (b) (4), (b) (6)      | 02 Mar 2021 15:39:35 |
|                           |                       |                      |
| User entered 'No (N)'     | System                | 02 Mar 2021 15:38:31 |

**US3902021**

**Folder: SAE USA-US210-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:17:24**

[Investigator's First Name](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Murray Kimmel (b) (4) | 30 Mar 2021 18:10:57 |
|                           |                       |                      |
| Reviewed for Safety.      | (b) (4), (b) (6)      | 02 Mar 2021 15:39:35 |
|                           |                       |                      |
| User entered 'Murray'     | System                | 02 Mar 2021 15:38:31 |

**US3902021**

**Folder: SAE USA-US210-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:17:24**

[Investigator's Last Name](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Murray Kimmel (b) (4) | 30 Mar 2021 18:10:57 |
|                           |                       |                      |
| Reviewed for Safety.      | (b) (4), (b) (6)      | 02 Mar 2021 15:39:35 |
|                           |                       |                      |
| User entered 'Kimmel'     | System                | 02 Mar 2021 15:38:31 |

**US3902021**

**Folder: SAE USA-US210-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:17:24**

[Investigator Country](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Murray Kimmel (b) (4) | 30 Mar 2021 18:10:57 |
|                           |                       |                      |
| Reviewed for Safety.      | (b) (4), (b) (6)      | 02 Mar 2021 15:39:35 |
|                           |                       |                      |
| User entered 'US'         | System                | 02 Mar 2021 15:39:24 |

**US3902021**

**Folder: SAE USA-US210-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:17:24**

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '2' | System | 18 Mar 2021 16:40:23 |
| User entered '1' | System | 02 Mar 2021 15:39:24 |



**US3902021**

**Folder: SAE USA-US210-2021-MRNA-1273-P301000002**

**Form: Safety Report Form (1)**

**Generated On: 10 Jun 2021 10:17:24**

[Date of submission \(Pre-filled from custom function\)](#)

| Audit                            | User                  | Time (GMT)           |
|----------------------------------|-----------------------|----------------------|
| User signature succeeded.        | Murray Kimmel (b) (4) | 30 Mar 2021 18:10:57 |
|                                  |                       |                      |
| User entered '02/Mar/2021 10:39' | System                | 02 Mar 2021 15:39:24 |

US3902021

Folder: SAE USA-US210-2021-MRNA-1273-P301000002

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 10:17:24

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Murray Kimmel (b) (4) | 30 Mar 2021 18:10:57 |
|                           |                       |                      |
| Reviewed for Safety.      | (b) (4), (b) (6)      | 02 Mar 2021 15:39:35 |
|                           |                       |                      |
| User entered 'I'          | (b) (4), (b) (6)      | 02 Mar 2021 15:39:24 |
|                           |                       |                      |

**US3902021**

**Folder: SAE USA-US210-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:17:24**

[SAEID](#)

| Audit   | User                  | Time (GMT)           |
|---|-----------------------|----------------------|
| User signature succeeded.                             | Murray Kimmel (b) (4) | 30 Mar 2021 18:10:57 |
|   |                       |                      |
| Reviewed for Safety.                                  | (b) (4), (b) (6)      | 02 Mar 2021 15:39:31 |
|   |                       |                      |
| User entered<br>'USA-US210-2021-MRNA-1273-P301000002' | System                | 02 Mar 2021 15:38:31 |

**US3902021**

**Folder: SAE USA-US210-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:17:24**

**Serious**

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Murray Kimmel (b) (4) | 30 Mar 2021 18:10:57 |
|                           |                       |                      |
| Reviewed for Safety.      | (b) (4), (b) (6)      | 02 Mar 2021 15:39:35 |
|                           |                       |                      |
| User entered 'Yes (Y)'    | System                | 02 Mar 2021 15:38:31 |

**US3902021**

**Folder: SAE USA-US210-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:17:24**

[Death](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Murray Kimmel (b) (4) | 30 Mar 2021 18:10:57 |
|                           |                       |                      |
| Reviewed for Safety.      | (b) (4), (b) (6)      | 02 Mar 2021 15:39:35 |
|                           |                       |                      |
| User entered 'No (N)'     | System                | 02 Mar 2021 15:38:31 |

**US3902021**

**Folder: SAE USA-US210-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:17:24**

[Life threatening](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Murray Kimmel (b) (4) | 30 Mar 2021 18:10:57 |
|                           |                       |                      |
| Reviewed for Safety.      | (b) (4), (b) (6)      | 02 Mar 2021 15:39:35 |
|                           |                       |                      |
| User entered 'No (N)'     | System                | 02 Mar 2021 15:38:31 |

**US3902021**

**Folder: SAE USA-US210-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:17:24**

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Murray Kimmel (b) (4) | 30 Mar 2021 18:10:57 |
|                           |                       |                      |
| Reviewed for Safety.      | (b) (4), (b) (6)      | 02 Mar 2021 15:39:35 |
|                           |                       |                      |
| User entered 'Yes (Y)'    | System                | 02 Mar 2021 15:38:31 |

**US3902021**

**Folder: SAE USA-US210-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:17:24**

[Persistent or significant disability or incapacity](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Murray Kimmel (b) (4) | 30 Mar 2021 18:10:57 |
|                           |                       |                      |
| Reviewed for Safety.      | (b) (4), (b) (6)      | 02 Mar 2021 15:39:35 |
|                           |                       |                      |
| User entered 'No (N)'     | System                | 02 Mar 2021 15:38:31 |



**US3902021**

**Folder: SAE USA-US210-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:17:24**

[Congenital anomaly or birth defect](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Murray Kimmel (b) (4) | 30 Mar 2021 18:10:57 |
|                           |                       |                      |
| Reviewed for Safety.      | (b) (4), (b) (6)      | 02 Mar 2021 15:39:35 |
|                           |                       |                      |
| User entered 'No (N)'     | System                | 02 Mar 2021 15:38:31 |

**US3902021**

**Folder: SAE USA-US210-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:17:24**

[Other medically important event](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Murray Kimmel (b) (4) | 30 Mar 2021 18:10:57 |
|                           |                       |                      |
| Reviewed for Safety.      | (b) (4), (b) (6)      | 02 Mar 2021 15:39:35 |
|                           |                       |                      |
| User entered 'No (N)'     | System                | 02 Mar 2021 15:38:31 |

**US3902021**

**Folder: SAE USA-US210-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:17:24**

[Investigator's First Name](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Murray Kimmel (b) (4) | 30 Mar 2021 18:10:57 |
|                           |                       |                      |
| Reviewed for Safety.      | (b) (4), (b) (6)      | 02 Mar 2021 15:39:35 |
|                           |                       |                      |
| User entered 'Murray'     | System                | 02 Mar 2021 15:38:31 |

**US3902021**

**Folder: SAE USA-US210-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:17:24**

[Investigator's Last Name](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Murray Kimmel (b) (4) | 30 Mar 2021 18:10:57 |
|                           |                       |                      |
| Reviewed for Safety.      | (b) (4), (b) (6)      | 02 Mar 2021 15:39:35 |
|                           |                       |                      |
| User entered 'Kimmel'     | System                | 02 Mar 2021 15:38:31 |

**US3902021**

**Folder: SAE USA-US210-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:17:24**

[Investigator Country](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Murray Kimmel (b) (4) | 30 Mar 2021 18:10:57 |
|                           |                       |                      |
| Reviewed for Safety.      | (b) (4), (b) (6)      | 02 Mar 2021 15:39:35 |
|                           |                       |                      |
| User entered 'US'         | System                | 02 Mar 2021 15:39:24 |

**US3902021**

**Folder: SAE USA-US210-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:17:24**

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '2' | System | 18 Mar 2021 16:40:23 |
| User entered '1' | System | 02 Mar 2021 15:39:24 |

**US3902021**

**Folder: SAE USA-US210-2021-MRNA-1273-P301000002**

**Form: Safety Report Form (2)**

**Generated On: 10 Jun 2021 10:17:24**

[Date of submission \(Pre-filled from custom function\)](#)

| Audit                            | User                  | Time (GMT)           |
|----------------------------------|-----------------------|----------------------|
| User signature succeeded.        | Murray Kimmel (b) (4) | 30 Mar 2021 18:10:57 |
|                                  |                       |                      |
| User entered '18/Mar/2021 12:40' | System                | 18 Mar 2021 16:40:23 |

US3902021

Folder: SAE USA-US210-2021-MRNA-1273-P301000002

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 10:17:24

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Murray Kimmel (b) (4) | 30 Mar 2021 18:10:57 |
|                           |                       |                      |
| User entered 'I'          | (b) (4), (b) (6)      | 18 Mar 2021 16:40:23 |
|                           |                       |                      |